WISEWOMAN Guidance Document: Interpretation of Legislative Language and Existing Policies and Documents

Table of Contents

Mission of WISEWOMAN

Provide low-income, underinsured, or uninsured 40- to 64-year-old women with the knowledge and skills needed to improve diet, physical activity, and other life habits to prevent, delay, or control cardiovascular and other chronic diseases.

Abbreviations and Acronyms

Below is a list of abbreviations and acronyms that are commonly used in the WISEWOMAN program.

ADA	American Diabetes Association
ATP III	National Cholesterol Education Program, Adult Treatment Panel III Report (NCEP, 2001)
CDC	Centers for Disease Control and Prevention
CLIA	Clinical Laboratory Improvement Amendments
CHD	coronary heart disease
CVD	cardiovascular disease
CVH	cardiovascular health
DASH	Dietary Approaches to Stop Hypertension
DCPC	Division of Cancer Prevention and Control
DDT	Division of Diabetes Translation
DHHS	Department of Health and Human Services
DNPA	Division of Nutrition and Physical Activity
FPG	fasting plasma glucose
GPRA	Government Performance and Results Act
HBP	high blood pressure
HRSA	Health Resources and Services Administration
HTN	Hypertension
IRB	Institutional Review Board
JNC VI	Sixth Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC VI, 1997)

MDE	minimum data element
MNT	medical nutrition therapy
NBCCEDP	National Breast and Cervical Cancer Early Detection Program
NCCDPHP	National Center for Chronic Disease Prevention and Health Promotion
NCEP	National Cholesterol Education Program
NHLBI	National Heart, Lung, Blood Institute
NIH	National Institutes for Health
OGTT	oral glucose tolerance test
PHS	Public Health Service
PRC	Prevention Research Center
RFA	request for application
SIP	special interest project
TLC	therapeutic lifestyle changes
WISEWOMAN	Well-Integrated Screening and Evaluation for Women Across the Nation

Executive Summary

In 1993 Congress authorized the Centers for Disease Control and Prevention (CDC) to establish the WISEWOMAN demonstration program to extend the services provided within the National Breast and Cervical Cancer Early Detection Program (NBCCEDP) framework. The NBCCEDP and WISEWOMAN programs, engendered at different times by the same "parent" (i.e., the same public health act), are "sister" programs administered by two different CDC Divisions. The NBCCEDP is an established, nationwide program that since 1990 has provided cervical cancer screening for 18- to 64-year-old women and breast cancer screening for 40- to 64-year-old women. Since 1995 WISEWOMAN, a demonstration program available in 11 states, has provided preventive services to 40- to 64-year-old women who participate in the NBCCEDP. Whereas the NBCCEDP focuses on finding cancer as early as possible through testing, WISEWOMAN aims to reduce heart disease and other chronic disease risk factors through screening and lifestyle interventions that target blood pressure, cholesterol, diet, physical activity, and smoking status.

The WISEWOMAN demonstration program serves two purposes. The demonstration allows Congress to see whether it is practical to offer additional preventive services through the established NBCCEDP framework. Also, the benefits of such services for low-income and uninsured women are measured.

As parts of this demonstration program, CDC encourages the existing projects to be creative and flexible in developing models that will be effective in decreasing risk factors for lowering cardiovascular disease and other preventable chronic diseases through nutrition, physical activity, and tobacco cessation interventions. Because projects need maximum flexibility, only those policies needed to effectively administer and meet legislative requirements have been developed. Summaries of these policies follow, but policy details are provided in various chapters of this guidance document. New policies will be developed as needed with input from WISEWOMAN stakeholders and consultants. See Appendix A for the WISEWOMAN policy development framework.

This WISEWOMAN guidance document provides background information, explanations of legislative requirements, and WISEWOMAN cooperative agreement and program management policies. Appendix B contains definitions of key terms pertinent to the WISEWOMAN program. All WISEWOMAN project staff are encouraged to become familiar with this manual. As with any program, the manual is a work in progress. As new policies and supporting materials are developed, they will be made available.

Summary of WISEWOMAN Policies

Chapter 1: Legislative Requirements

1.1 Governing Legislation

WISEWOMAN projects must follow the same legislative requirements detailed for the NBCCEDP projects in 42 U.S.C. § 300k of the Public Health Service Act, as amended.

1.2 Requirement of Matching Funds

Projects must make available nonfederal contributions (in cash or in kind and as authorized in legislative provisions) toward such costs in an amount equal to but not less than $1 for each $3 of federal funds provided in the grant. Such contributions may be made directly or through donations from public or private entities.

1.3 Budget Allocation Requirement: 60 Percent/40 Percent Distribution

At least 60 percent of cooperative agreement funds will be expended for screening, diagnostic tests, laboratory fees, health education, intervention sessions, tracking, follow-up, and support services for screening, diagnosis, and intervention. The remaining 40 percent or less will be expended for public education programs, professional education, quality assurance, surveillance. evaluation, and administration [42 U.S.C. 300k(a) and 300m(a) of the Public Health Service Act, as amended].

1.4 Budget Allocation Requirement: Administrative Expenses

Not more than 10 percent of funds will be expended annually for administrative expenses [42 U.S.C. 300n(f) of the Public Health Service Act, as amended]. Administrative expenses comprise a portion of the 40 percent component of the budget and are in lieu of and replace indirect costs.

1.5 Legislation and Medication

WISEWOMAN funds cannot be used for any treatment, including medications.

Chapter 2: Building Capacity

2.1 Staffing Requirements

Projects will appoint or hire at least two professional staff members to work full-time on WISEWOMAN (one of whom will be a full-time coordinator). Projects will develop a WISEWOMAN evaluation team with appropriate experience and training.

2.2 Budget Requirements for Staff Development

Projects need to budget each year for the following:

- Up to two persons to attend the Nutrition and Public Health Course that is sponsored by the University of North Carolina Prevention Research Center and the CDC. This is a 5-day course. For more information see www.hpdp.unc.edu/nph. Future topics and place to be determined. This mandatory course provides training on WISEWOMAN best practices.

- Up to two persons to participate in the annual WISEWOMAN Project Coordinators Meeting that is held in conjunction with the NCCDPHP Annual Chronic Disease Conference (4 days). Details are provided at www.cdc.gov/ nccdphp/conference/index.htm. This is a mandatory meeting for the purpose of sharing projects' successes and challenges.

- Either one person to attend the Physical Activity and Public Health Course that is sponsored by the University of South Carolina Prevention Research Center and the CDC. This is an 8-day postgraduate course on research directions and strategies and a 6-day practitioner's course on community interventions. For more information see http://prevention.sph.sc.edu/Seapines/index.htm. Or one person to participate in a non–CDC-sponsored professional meeting directly relevant to the program.

2.3 Training Plans

A description of screening and intervention training plans must be included in project protocols that the CDC project officer must approve. For additional protocol guidance, see Chapter 7.

Chapter 3: Adherence to National Clinical Care Guidelines and Program Guidelines

3.1 Provider Compliance with National Clinical Care Guidelines

WISEWOMAN strongly encourages projects to contract only with providers who agree to follow national clinical care guidelines.

3.2 Professional Education – National Clinical Care Guidelines

To promote adherence to national clinical care guidelines, WISEWOMAN funds can be used to provide professional education on the use of guidelines.

3.3 WISEWOMAN-funded Case Management Eligibility

Although WISEWOMAN supports the use of case management to improve adherence to national clinical care guidelines, WISEWOMAN-funded case management services should be offered only to women who have alert values. Use of WISEWOMAN federal funds for case management of women without alert values is strongly discouraged. WISEWOMAN-funded case management services will conclude when a client either initiates treatment or is no longer eligible for the WISEWOMAN program.

Chapter 4: Screening, Referral, and Tracking

4.1 Allowable Office Visits

WISEWOMAN funds can be used to reimburse for one screening office visit and one diagnostic office visit per year for each participant.

4.2 Allowable Screening Tests

WISEWOMAN funds can be used for the following tests: resting pulse, blood pressure, serum total cholesterol (nonfasting), HDL-cholesterol (nonfasting), height and weight measurements, automated blood chemistry (to assess blood glucose, potassium, calcium, creatinine, uric acid, triglyceride, or micronutrient levels), urine analysis (including urine cotinine), and paper and pencil tests, interviews, or computerized methods that measure level of physical activity, dietary intake, smoking,

osteoporosis risk status, immunization status, or other chronic disease risk factors or preventable health problems.

If a woman is fasting at her screening encounter, a fasting lipoprotein analysis should be used to determine cholesterol level. Additional cholesterol testing will not be reimbursable during that 12-month period as only one lipoprotein analysis per year is allowed.

4.3 Allowable Diagnostic Tests

WISEWOMAN funds can be used for the following diagnostic tests: fasting lipoprotein panel and fasting plasma glucose (FPG) measurement or oral glucose tolerance test (OGTT). One each per year per participant is allowed. The use of program funds for other diagnostic tests will require substantial justification by the project.

4.4 Medical Referral for Women with Abnormal Values

A major responsibility of WISEWOMAN project staff is to ensure that women with abnormal screening values are referred to a health care provider for appropriate diagnostic examinations in accordance with national and program guidelines.

Projects will track information to determine the mean number of days from the screening visit to referral and the mean from the screening visit to the diagnostic visit. This information, which does not need to be submitted to CDC, is used by the project to detect problems with the referral system.

4.5 Requirement for Annual Rescreens

A system is in place to track all WISEWOMAN participants, regardless of screening results, and to remind them to return for annual rescreens. Annual rescreening will consist of the same screening tests that were completed at baseline and will use the same health behavior questions asked during the initial visit (these are reported as MDEs). A minimum of 75 percent of all women initially screened will return for at least one annual rescreen per CDC performance standard.

4.6 Medical Referral for Women with Alert Values

A woman with an alert value is referred to a health care provider immediately or within 1 week, depending on the clinical situation, in accordance with national and program guidelines. Projects are encouraged to provide support services to women with alert values to ensure receipt of follow-up medical care and treatment. Documentation of referral and receipt of care and treatment for each woman with an alert value is reported to CDC quarterly.

Chapter 5: Lifestyle Intervention

5.1 Approval Requirement for Lifestyle Intervention

WISEWOMAN interventional plans should be detailed in a protocol developed during the planning phase and must be submitted to CDC project officers for approval before the start of screening and intervention. In addition, the CDC Institutional Review Board must approve an enhanced project's plans.

5.2 Lifestyle Intervention Follow-up

WISEWOMAN funds may be used to provide follow-up services to promote complete attendance at and adherence to the project's standardized intervention program. To meet the CDC performance standard, 75 percent of eligible women must attend at least one intervention session, and 60 percent must complete all intervention sessions.

5.3 Tracking Participation of Lifestyle Intervention

Projects will develop a system for analysis of participant data, first, to ensure that a woman enrolled in the intervention receives the complete interventional program in a timely manner and, second, to assist in program evaluation.

Chapter 6: Medication

6.1 Ensuring Access to Medication

A system to ensure access to medication must be described in a protocol that is approved by a CDC project officers before the start of screening and intervention.

Chapter 7: Protocol Policy

7.1 Program Protocol Requirements

Projects must develop protocols that contain detailed descriptions of WISEWOMAN activities. The CDC project officer must approve protocols before a project initiates screening or intervention activities.

Chapter 8: Evaluation

8.1 Minimum Data Element Reporting

Projects should collect and report minimum data elements and cost information in the format suggested by CDC to CDC or its contractor twice a year.

Report due on April 15	Covering dates through December 31
Report due on October 15	Covering dates through June 30

8.2 Quarterly Progress Reports

Quarterly progress reports are due 30 days after the reporting period, as follows:

October 31 - for the reporting period July 1 – September 30

January 31 - for the reporting period October 1 – December 31

April 30 - for the reporting period January 1 – March 31

July 31 - for the reporting period April 1 – June 30

Chapter 1: Legislative Requirements

Background

WISEWOMAN was authorized as a program in 1993 through a legislative supplement to the Breast and Cervical Cancer Mortality Prevention Act of 1990 (Public Law 101-354) that established the CDC's National Breast and Cervical Cancer Early Detection Program (NBCCEDP). The relevant legislative language can be found at http://www.cdc.gov/wisewoman/legislationhighlight.htm.

WISEWOMAN Authorization Language

The WISEWOMAN program's authorization language (with amendments in bold italics) follows:

42 U.S.C. § 300n-4a. Supplemental grants for additional preventive health services

(a) Demonstration projects. In the case of States receiving grants under section 1501 [42 U.S.C. § 300k], the Secretary, acting through the Director of the Centers for Disease Control and Prevention, may make grants to not more than 3 such States to carry out demonstration projects for the purpose of—

(1) providing preventive health services in addition to the services authorized in such section, including screenings regarding blood pressure and cholesterol, and including health education;

(2) providing appropriate referrals for medical treatment of women receiving services pursuant to paragraph (1) and ensuring, to the extent practicable, the provision of appropriate follow-up services; and

(3) evaluating activities conducted under paragraphs (1) and (2) through appropriate surveillance or program-monitoring activities.

(b) Status as participant in program regarding breast and cervical cancer. The Secretary may not make a grant under subsection (a) unless the State involved agrees that services under the grant will be provided only through entities that are screening women for breast or cervical cancer pursuant to a grant under section 1501 [42 U.S.C. § 300k].

(c) Applicability of provisions of general program. This title [42 U.S.C. §§ 300k et seq.] applies to a grant under subsection (a) to the same extent and in the same

manner as such title applies to a grant under section 1501[42 U.S.C. § 300k].

(d) Funding.

(1) In general. Subject to paragraph (2), for the purpose of carrying out this section, there are authorized to be appropriated $ 3,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 ***through 2003 (Women's Health Research and Prevention Amendments of 1998, Public Law 105-340).***

(2) Limitation regarding funding with respect to breast and cervical cancer. The authorization of appropriations established in paragraph (1) is not effective for a fiscal year unless the amount appropriated under section 1510(a) [42 U.S.C. § 300n-5(a)] for the fiscal year is equal to or greater than $ 100,000,000.

Subsequent provisions to expand WISEWOMAN to not more than 15 states come from the Committee Report - House Rpt. 106-1033 - Making Omnibus Consolidated and Emergency Supplemental Appropriations for Fiscal Year 2001 (HR 196-1033, 2001).

Legislative Requirement Policy 1.1

Governing Legislation

WISEWOMAN projects must follow the same legislative requirements as detailed for the NBCCEDP projects in 42 U.S.C. § 300k of the Public Health Service Act, as amended.

Legislative Requirement Policy 1.2

Requirement of Matching Funds

Projects must make available nonfederal contributions (in cash or in kind and as authorized in legislative provisions) toward such costs in an amount equal to but not less than $1 for each $3 of federal funds provided in the grant. Such contributions may be made directly or through donations from public or private entities.

Legislative Requirement Policy 1.3

Budget Allocation Requirement: 60 Percent/40 Percent Distribution

At least 60 percent of cooperative agreement funds will be expended for screening, diagnostic tests, laboratory fees, health education, intervention sessions, tracking, follow-up, and support services for screening, diagnosis, and intervention, The remaining 40 percent or less will be expended for public education programs, professional education, quality assurance, surveillance. evaluation, and administration [42 U.S.C. 300k(a) and 300m(a) of the Public Health Service Act, as amended].

A framework for determining the 60 percent or 40 percent distribution of cooperative agreement funds is provided at the end of this chapter in Table 1.1.

Legislative Requirement Policy 1.4

Budget Allocation Requirement: Administrative Expenses

Not more than 10 percent of funds will be expended annually for administrative expenses [42 U.S.C. 300n(f) of the Public Health Service Act, as amended]. Administrative expenses comprise a portion of the 40 percent component of the budget and are in lieu of and replace indirect costs.

Legislative Requirement Policy 1.5

Legislation and Medication

WISEWOMAN funds cannot be used for any treatment, including medications**.**

Framework for Determining 60 Percent/40 Percent Distribution

Table 1.1 - Framework for Determining 60 Percent/40 Percent Distribution*

60 Percent	40 Percent
Screening Services	**Public Education**
Annual screening office visit (reimbursement of health care provider time or fees for office visits)	Media
Fasting lipoprotein profile or serum total cholesterol and HDL-C (if nonfasting)	Materials development
Blood glucose	Coalition support/travel
Assessments (to include MDEs)	Focus groups
See RFA for other allowable tests	Group outreach
Diagnostic Services	**Professional Education**
One diagnostic visit is allowed for a woman with an abnormal value (reimbursement of health care provider time or fees for office visits)	Conferences
Fasting lipoprotein profile (total cholesterol, LDL, HDL, and triglycerides)	Training
Fasting plasma glucose	Newsletters or updates for providers
Oral glucose tolerance test (OGTT)	
Laboratory Fees	**Quality Assurance**
Lab costs for screening and diagnostic tests (see above)	Audits and monitoring activities that identify whether program guidelines and protocols are being followed
Lifestyle Intervention	**Surveillance and Evaluation**
Nutrition counseling	Tracking and monitoring aggregate data
Physical activity counseling	Project evaluation
Tobacco cessation counseling	
Tracking, Follow-up, and Support Services for Screening, Diagnosis, and Intervention	**All Other Functions**
Translation for participant	Management and planning
Transportation for participant	Administrative costs and personnel
1:1 Outreach	Curriculum development
Participant intake	Reporting
Participant tracking	
Intervention coordination for participant	
Case management for women with alert values	
Incentives for participant	

Staff time should be partitioned according to the activities that they conduct. For example, administrative duties belong in the 40 percent category and one-on-one activities that can be tied to an individual participant belong in the 60 percent category.

* Does not apply to nonfederal matching funds.

The full legislative language is available at http://www.cdc.gov/wisewoman/legislationhighlight.htm.

Chapter 2: Building Capacity to Prevent Cardiovascular and Other Chronic Diseases in Vulnerable Populations

Background

Preventing a chronic disease requires project staff to understand its early detection, methods of implementing effective lifestyle interventions in vulnerable populations, systems that provide good quality medical care for underserved women, and methods for assessing whether programs are effective. Some state health departments, tribal agencies, and territorial health agencies will already have staff who possess these skills and knowledge; however, projects in areas without such resources may need to either recruit new staff or train existing staff to attain this expertise.

Building State/Tribal/Territorial Capacity

The following staffing and budget requirements are used to facilitate the building of state/tribal/territorial capacity to carry out WISEWOMAN activities.

Building Capacity Policy 2.1

Staffing Requirements

Projects will appoint or hire at least two professional staff members to work full-time on WISEWOMAN (one of whom should be a full-time coordinator). Projects will develop a WISEWOMAN evaluation team with appropriate experience and training.

Building Capacity Policy 2.2

Budget Requirements for Staff Development

Projects will budget each year for:

- Up to two persons to attend the 5-day Nutrition and Public Health Course that is sponsored by the University of North Carolina Prevention Research Center and the CDC. For more information see www.hpdp.unc.edu/nph. Future topics and place to be determined. This mandatory course provides training on WISEWOMAN best practices.

- Up to two persons to participate in the annual WISEWOMAN Project Coordinators Meeting that is held in conjunction with NCCDPHP Annual Chronic Disease Conference (4 days). Details are provided at www.cdc.gov/ nccdphp/conference/index.htm. Thi is a mandatory meeting for the purpose of sharing projects' successes and challenges.

- Either one person to attend the Physical Activity and Public Health Course that is sponsored by the University of South Carolina Prevention Research Center and the CDC. This is an 8-day postgraduate course on research directions and strategies and a 6-day practitioner's course on community interventions. For more information, see http://prevention.sph.sc.edu/Seapines/index.htm. Or one person to participate in a non–CDC-sponsored professional meeting directly relevant to the program.

Training WISEWOMAN Staff and Contractors

In the screening protocol, projects will describe their training strategies with regard to screening standards. This protocol will include assurances that staff members have received training specific to their responsibilities, have access to consultation from appropriate health professionals, and have adequate supervision. The protocol will describe how providers will follow the screening guidelines provided in the National Cholesterol Education Program, Adult Treatment Panel III Report (NCEP, 2001) and the Sixth Report of the Joint

National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC VI, 1997), how this will be monitored, and the steps to be taken when guidelines are not followed.

In the lifestyle intervention protocol, projects will describe the quality assurance efforts for implementing the lifestyle intervention. The quality assurance plan would likely contain information on training project staff to implement an effective intervention according to federal and project standards.

Building Capacity Policy 2.3

Training Plans

A description of screening and intervention training plans must be included in project protocols that the CDC project officer must approve. For additional protocol guidance, see Chapter 7, Program Protocols.

Additional Training Recommendations Based on Lessons Learned

Some lessons learned from the three original WISEWOMAN programs are presented below.

Training program staff at their facility (i.e., on-site) is very effective, although labor-intensive. If on-site training is not feasible, the next best option may be to train staff from several programs in the same region. With any method of training (face-to-face, videoconferencing, etc.), make sure that the staff members who are most involved with the project attend the training. Training should include a comprehensive training manual, use of small group discussions, role-plays, demonstration, discussion of counseling strategies and social support mechanisms, and other techniques suited to adult learners. To enhance learning, make the training as interactive and hands-on as possible. Frequent opportunities for refresher training should be made available.

Chapter 3: Adherence to National Clinical Care Guidelines and Program Guidelines

Background

To identify women at risk for CVD, WISEWOMAN projects screen participants for high cholesterol and high blood pressure. At a minimum, the National Cholesterol Education Program, Adult Treatment Panel III Report (NCEP, 2001) and the Sixth Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC VI, 1997) will guide the screening and intervention services offered by the project. These two documents are also known as ATP III and JNC VI. Further, although all projects screen for poor diet, physical inactivity, and tobacco use, some projects also screen for diabetes. Table 3.1 provides additional national guidelines that projects should follow to address these CVD risk factors.

Table 3.1 - National Guidelines Aimed at Modifiable CVD Risk Factors

Risk Factor	Guidelines and Web Links
Hypertension	Follow Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC VI, 1997) http://www.nhlbi.nih.gov/guidelines/hypertension/jnc6.pdf
Abnormal cholesterol	National Cholesterol Education Program, Adult Treatment Panel III Report (NCEP, 2001) http://rover2.nhlbi.nih.gov/guidelines/cholesterol/index.htm
Atherogenic diet increases risk for CVD and diets high in plant foods and fiber are associated with a decreased risk	Promote ATP-III TLC diet principles (NCEP, 2001) Promote DASH diet principles (JNC VI, 1997)
Low levels of physical activity	Follow Surgeon General's recommendations for physical activity (HHS, 1996) http://www.cdc.gov/nccdphp/sgr/contents.htm
Overweight and obesity	Follow Obesity Education Initiative guidelines for

Risk Factor	Guidelines and Web Links
	weight management (NIH, 1998) http://www.nhlbi.nih.gov/about/oei/ Follow Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults (NIH, 1998) http://www.nhlbi.nih.gov/guidelines/obesity/ob_home.htm
Tobacco	Follow US Department of Health and Human Services Clinical Practice Guideline: Treating Tobacco Use and Dependence (PHS, 2000) http://www.surgeongeneral.gov/tobacco/default.htm
Diabetes Diabetes counts as a CHD risk equivalent (NCEP, 2001)	Follow American Diabetes Association, Volume 25 Supplement 1, Clinical Practice Recommendations 2002 (ADA, 2002) http://care.diabetesjournals.org/content/vol25/suppl_1/

Promoting Adherence to National Clinical Care Guidelines

WISEWOMAN project staff should work with providers to assure that national guidelines are followed. Health care facilities, as part of providing good medical care, should adopt strategies to ensure adherence to these guidelines. This chapter addresses methods to be used to improve adherence to the national guidelines and the role of WISEWOMAN in so adhering.

Both ATP III and JNC VI include several strategies that can be used to improve adherence. Although the focus of ATP III is on lipid management and JNC VI is on hypertension management, their methods for promoting adherence can be generalized. The tables below list some of these methods.

Table 3.2 - Interventions to Improve Adherence (NCEP, 1997, p. ix-11)

Focus on the Patient (Use as Many Interventions as Possible)

- Simplify medication regimens.
- Provide explicit patient instructions and use good counseling techniques to teach the patient how to follow the prescribed treatment.
- Encourage the use of prompts to help patients remember treatment regimens.
- Use systems to reinforce adherence and maintain contact with the patient.
- Encourage the support of family and friends.
- Reinforce and reward adherence.
- Increase patient visits for persons unable to achieve their treatment goal.
- Increase convenience of and access to care.
- Involve patients in their own care through self-monitoring.

Focus on the Physician and Medical Office

- Teach physicians to implement lipid treatment guidelines.
- Use reminders to prompt physicians to attend to lipid management.
- Identify a patient advocate in the office to help deliver or to prompt care.
- Use patients to prompt preventive care.
- Develop a standardized treatment plan to structure care.
- Use feedback from past performance to foster change in future care.
- Remind patients of appointments and follow up on missed appointments.

Focus on the Health Delivery System

- Provide lipid management through a lipid clinic.
- Utilize case management by nurses.
- Deploy telemedicine.
- Use the collaborative care of pharmacists.
- Implement critical care pathways in hospitals.

Table 3.3 - The Clinicians' Abridged Pocket Guide to Enhancing Adherence (NCEP, 1997, p. ix-11)

- Keep the regimen as simple as possible.
- Give the patient clear instructions.
- Discuss adherence for at least a few seconds at each visit.
- Concentrate on those who don't reach treatment goals.
- Always call patients who miss visit appointments.
- Use two or more strategies for those who miss treatment goals.

Table 3.4 - General Guidelines to Improve Patient Adherence to Antihypertensive Therapy (JNC VI, 1997, p. 38).

- Be aware of signs of patient nonadherence to antihypertensive therapy.
- Establish the goal of therapy: to reduce blood pressure to nonhypertensive levels with minimal or no adverse effects.
- Educate patients about the disease and involve them and their families in its treatment.
- Have patients measure their blood pressure at home.
- Maintain contact with patients; consider telecommunication.
- Keep care inexpensive and simple.
- Encourage lifestyle modifications.
- Integrate pill-taking into routine activities of daily living.
- Prescribe medications according to pharmacological principles, favoring long-acting formulations.
- Be willing to stop unsuccessful therapy and to try a different approach.
- Anticipate adverse effects and adjust therapy to prevent, minimize, or ameliorate side effects.
- Continue to add effective and tolerated drugs, stepwise, in sufficient doses to achieve the goal of therapy.
- Encourage a positive attitude about achieving therapeutic goals.
- Consider using nurse case management.

In the protocol that describes linkage to medical care (see Chapter 7, Program Protocols), projects should include a copy of their provider contract to show that national and WISEWOMAN guidelines will be followed. In addition, projects should work with providers who agree to ensure appropriate management of

women with abnormal values. The protocol should also describe the training plan and related audits.

Adherence to Guidelines 3.1

Provider Compliance with National Clinical Care Guidelines

WISEWOMAN strongly encourages projects to contract only with providers who agree to follow national clinical care guidelines.

Adherence to Guidelines 3.2

Professional Education – National Clinical Care Guidelines

To promote adherence to national clinical care guidelines, WISEWOMAN funds can be used to provide professional education on the use of guidelines.

Program Guidelines

The legislative provisions for WISEWOMAN are contained in the Breast and Cervical Cancer Mortality Prevention Act of 1990 (P.L. 101-354). These provisions did not refer specifically to case management as a program component. However, in October 1998, Congress modified the legislative authority of the program to include case management. The amendment, contained in the Women's Health Research and Prevention Amendments of 1998, calls for programs "to ensure, **to the extent practicable**, the provision of appropriate follow-up services and support services such as case management " (PL 105-340, 1998).

WISEWOMAN-funded Case Management

As noted in Tables 3.2 and 3.4, case management is one strategy to improve adherence. This chapter provides guidance on the use of funding for case management services. Guidance on other support services such as client outreach, tracking, and follow-up is in Chapter 4, Screening, Referral, and Tracking.

WISEWOMAN defines case management the same way that the National Breast and Cervical Cancer Early Detection Program Policies & Procedures Manual defines it (NBCCEDP, 2000, p. iv-56):

> A program component that involves establishing, brokering, and sustaining a system of available clinical (screening, diagnostic, and treatment) and essential support services for all NBCCEDP enrolled women who would ultimately be assessed to need case management services. Throughout this policy, the term "client" refers to women in the NBCCEDP program who have a demonstrated need for case management, the most intensive intervention in the continuum of care. CDC expects that the proportion of case management clients in the program will be small compared with all the women being served by the NBCCEDP.

Case management is, as this statement indicates, the most intensive support service. It consists of establishing, brokering, and sustaining a system of clinical and essential support services for all women with alert values. Professional standards of case management should be applied if this service is undertaken. The key elements of individual case management as identified in the NBCCEDP Policies and Procedures Manual are as follows.

Key Elements of Individual Case Management (NBCCEDP, 2000, p. iv-57).

1. A cooperative effort between client and case manager to examine client's needs
2. Development of a written plan
3. Brokerage, coordination, and referral
4. Reassessments of the plan
5. Promotion of self-sufficiency
6. Evaluation of quality of plan

Because 60 percent to 80 percent of WISEWOMAN participants may have abnormal screening values, the use of federal funds to provide clinical case management to all women with abnormal screening values is neither practicable nor cost-efficient. Therefore, WISEWOMAN-funded case management services should be offered only to women with alert values. A section on alert values for the WISEWOMAN Program appears at the end of this chapter.

Support for Policy 3.3, found under Use of Funds in Program Announcement 00115, 99135, and 01098, states that funds should be expended for screening, for appropriate referral for medical treatment, and to ensure, *to the extent practicable*, the provision of appropriate follow-up services and support services such as case management.

Adherence to Guidelines Policy 3.3

WISEWOMAN-funded Case Management Eligibility

Although WISEWOMAN supports the use of case management to improve adherence to national clinical care guidelines, WISEWOMAN-funded case management services should be offered only to women with alert values. Use of WISEWOMAN federal funds for case management of women without alert values is strongly discouraged. WISEWOMAN-funded case management services will conclude when a client initiates treatment or is no longer eligible for the WISEWOMAN program.

Alert Values for WISEWOMAN Program

"Alert values" were established during the first phase of WISEWOMAN (1995-1998) after a review of other national research studies to determine how those studies managed persons with dangerously high blood chemistry measurements. For cholesterol and glucose, WISEWOMAN modeled the alert values on the "panic values" established by the National Health and Nutrition Examination Survey III (NHANES III).

The NHANES III defines panic values as ≥400 mg/dL for cholesterol and ≥375 mg/dL for glucose. With regard to extremely high blood pressure, which can be deadly if left untreated for even a short time, WISEWOMAN relied on the JNC-VI guidelines because of their clarity about clinical management of such extremely high values. The guidelines recommend that a systolic blood pressure ≥180 mm Hg or a diastolic blood pressure ≥110 mm Hg should be treated within 1 week. WISEWOMAN recognizes that with alert values for cholesterol (>400 mg/dL), a woman does not necessarily need emergency referral, but she does require referral for a diagnostic examination within 1 week.

To summarize, the following levels are considered alert values:

- Systolic blood pressure ≥180 mm Hg
- Diastolic blood pressure ≥110 mm Hg
- Blood glucose ≥375 mg/dL
- Cholesterol ≥400 mg/dL

Information about how to track alert values is in Chapter 4, Screening, Referral, and Tracking; how to report alert values is in Chapter 8, Evaluation.

Chapter 4: Screening, Referral, and Tracking

Background

WISEWOMAN began as a supplement to the legislation that authorizes NBCCEDP. This supplement allows the CDC to make cooperative agreements available for demonstration projects to provide preventive health services, including screening for elevated blood pressure and cholesterol, and to provide health education. As a result, WISEWOMAN projects develop and implement a chronic disease screening and lifestyle intervention program whose priority is to prevent cardiovascular disease.

Eligibility criteria for WISEWOMAN services were based on eligibility criteria for NBCCEDP mammography services. Therefore, WISEWOMAN services may be provided to 40 to 64 year-old women who are enrolled in the state's BCCEDP, of which 75 percent should be 50 to 64 years of age. These women are low-income (250% poverty or less), under-insured, or uninsured and represent ethnic and minority populations. This age restriction is considered necessary because of financial constraints that require thoughtful allocation of resources. The chances of developing heart disease increase as women grow older. As women approach the age of menopause, their risk of heart disease and stroke begins to rise and keeps rising with age (NCEP, 1997, p. ii-28).

The objective of screening for high blood pressure is to identify women likely to benefit from blood pressure reduction, which has been shown to lower the risk of cardiovascular disease (CVD), particularly stroke.

The objective of screening for high blood cholesterol is to identify women likely to benefit from a reduction in their elevated blood cholesterol, a major risk factor for coronary heart disease (CHD). Reducing blood cholesterol lowers the risk of CHD. Screening for diabetes remains controversial, as noted by the American Diabetes Association (ADA) in its Clinical Practice Recommendations 2002 (p. S23):

> Although there is ample scientific evidence showing that certain risk factors predispose individuals to development of diabetes, there is insufficient evidence to conclude that community screening is a cost-effective approach to reduce the morbidity and mortality associated with diabetes in presumably healthy individuals. While community screening programs may provide a means to enhance public awareness of the seriousness of diabetes and its complications, other less costly approaches may be more appropriate, particularly because the potential risks are poorly defined.

Thus, based on the lack of scientific evidence, community screening for diabetes, even in high-risk populations, is not recommended.

CDC's Division of Diabetes Translation has determined that diabetes screening provided through WISEWOMAN constitutes *opportunistic* screening because the participant is screened in a health care facility, often during a breast and cervical cancer screening office visit. It is not uncommon for WISEWOMAN participants to be at higher risk for diabetes due to age, weight, and physical inactivity status. Therefore, WISEWOMAN funds can be used for diabetes screening.

WISEWOMAN projects should work with a health care advisory committee or expert consultants to develop protocols and training on JNC VI, ATP III, and ADA clinical practice recommendations.

Another resource that projects are strongly encouraged to use when planning and implementing screening activities is UNC's WISEWOMAN monograph entitled "Integrating Cardiovascular Disease Prevention into Existing Health Services" (2001). To view or download this document, see www.hpdp/unc.edu/wisewoman.

Overview of Project Screening and Referral Responsibilities

The following flow diagram provides an overview of project responsibilities with regard to screening and referral. This program flow diagram was adapted from the UNC WISEWOMAN monograph.

Figure 4.1 Overview of Project Screening and Referral Responsibilities

During the baseline WISEWOMAN screening the following activities will occur:

- Participant signs consent form
- Baseline screening form is completed (to include MDEs for nutrition and physical activity)
- Baseline measures are taken, such as height, weight, blood pressure, cholesterol, and others as appropriate (e.g., plasma glucose)

For women found to have desirable screening values the following activities will occur:

1. she will receive her screening results,
2. be re-evaluated in one year,
3. and be encouraged to participate in a healthy lifestyle (which may include the WISEWOMAN intervention)

If the WISEWOMAN participant is found to have abnormal blood pressure, glucose, and/or cholesterol (abnormal value levels but not alert values) the following activities will occur:

1. The participant will be informed of her results.
2. The participant will receive medical referral, if indicated for:
    - Elevated blood pressure
    - Elevated cholesterol
    - Elevated blood glucose
    - Physical activity clearance (see UNC WW Manual page A-20)

If the WISEWOMAN participant is found to have an alert screening value then the following activities will occur:

1. The participant will receive a timely referral (as outlined in National Guidelines) to diagnostic and follow-up care and
2. Quarterly documentation in CDC progress report of percentage referred, timeliness of referral, and receipt of appropriate treatment.

After screening occurs the project should provide the lifestyle intervention to women with normal and/or abnormal screening values, per project protocol.

Enhanced WISEWOMAN projects are allowed to provide 6-Month Optional Follow-up Visit for Assessing Intervention Effectiveness. Activities include:

1. After intervention, repeat baseline measures for those who participated in intervention and
2. Provide information about test/screening results and
3. Medical referral is provided for women with abnormal values

All WISEWOMAN Projects (enhanced and standard) are to have women return for a Mandatory 12-Month Follow-up/Annual Re-evaluation. At which time the following activities occur:

1. Repeat baseline measures for all enrolled women (regardless of whether they attended intervention): weight, blood pressure, lipids, and blood glucose, if appropriate
2. Repeat baseline screening form (to include MDEs that contain nutrition and physical activity assessment)
3. Provide information about screening results to the participant
4. Medical referral for women with abnormal values

Providing WISEWOMAN-funded services to women already enrolled in a state's Breast and Cervical Cancer Early Detection Program results in WISEWOMAN

screening services being delivered in several different settings and in a variety of ways. For example, WISEWOMAN services might be offered in conjunction with an annual exam that includes a breast and cervical examination. Projects will work with their health care community to determine the best way to offer WISEWOMAN screening services. In addition, methods are needed to assure that women are screened annually for evaluation purposes.

Screening, Referral, Tracking, and Reporting Policy 4.1

Allowable Office Visits

WISEWOMAN funds may be used to reimburse for one screening office visit and one diagnostic office visit per year for each participant.

Screening and Diagnostic Tests

It is important to screen as many eligible women as possible for CVD risk factors. WISEWOMAN therefore allows for the use of both nonfasting and fasting cholesterol measurements for the purpose of determining whether a woman needs medical attention. WISEWOMAN supports the recommendation provided by the ATP III guidelines to use fasting lipid measurement, if scheduling allows. If a fasting lipid measurement is obtained during the screening exam, it is appropriate to consider the test as diagnostic in nature. The program will not pay for additional diagnostic visits or testing, as only one diagnostic test will be paid for annually. Tests that require the participant to fast are considered to be diagnostic tests and not screening tests.

Screening, Referral, Tracking, and Reporting Policy 4.2

Allowable Screening Tests

WISEWOMAN funds can be used for the following tests: resting pulse, blood pressure, serum total cholesterol (nonfasting), HDL-cholesterol (nonfasting), height and weight measurements, automated blood chemistry (to assess blood glucose, potassium, calcium, creatinine, uric acid, triglyceride, or micronutrient levels), urine analysis (including urine cotinine), and paper and pencil tests, interviews, or computerized methods that measure level of physical activity, dietary intake, smoking, osteoporosis risk status, immunization status, or other chronic disease risk factors or preventable health problems.

If a woman is fasting at her screening encounter, a fasting lipoprotein analysis should be used to determine cholesterol level. Additional cholesterol testing will not be reimbursable during that 12-month period as only one lipoprotein analysis per year is allowed.

Screening, Referral, Tracking, and Reporting Policy 4.3

Allowable Diagnostic Tests

WISEWOMAN funds can be used for the following diagnostic tests: fasting lipoprotein panel and fasting plasma glucose (FPG) measurement or oral glucose tolerance test (OGTT). One each per year per participant is allowed. The use of program funds for other diagnostic tests will require substantial justification by the project.

Risk Factor: High Blood Pressure

The *Sixth Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure* (1997) strongly encourages lifestyle modification to prevent high blood pressure, as definitive therapy for some and as adjunctive therapy for all persons with hypertension. WISEWOMAN supports the provision of the lifestyle intervention to all participants, not just those with abnormal screening results.

Project staff will strongly encourage health care providers receiving WISEWOMAN funds to use JNC VI recommendations to guide their clinical care for WISEWOMAN participants. NHLBI provides access to the full JNC VI report and a quick reference card (see Appendix C) that can be downloaded from http://www.nhlbi.nih.gov/guidelines/index.htm. It is recommended that health care providers use these materials to stratify hypertensive patients by blood pressure stage and cardiovascular risks and to determine the blood pressure goal and specific treatment. Refer to the full document for additional stratification and treatment recommendations.

Risk Factor: Elevated Cholesterol

The National Cholesterol Education Program (NCEP) Adult Treatment Panel III (ATP III) Report states that a clinical risk assessment has two goals: to identify persons who are at risk for accelerated atherogenesis and to identify those persons who are at higher risk for experiencing acute coronary syndrome because of established advanced atherosclerosis. A major new feature of ATP III is a focus on primary prevention of CHD in persons with multiple risk factors. Many people with multiple risk factors have a relatively high risk for CHD and will benefit from more intensive LDL-lowering treatment.

Projects receiving WISEWOMAN funds will strongly encourage their health care providers to use ATP III recommendations to guide their clinical care of WISEWOMAN participants with elevated cholesterol. Further, WISEWOMAN projects should work with their health care advisory committee to develop protocols and provide training on ATP III guidelines for their health care providers.

ATP III recommends a complete lipoprotein profile (total cholesterol, LDL cholesterol, HDL cholesterol, and triglycerides) as the preferred initial test, rather than screening for total cholesterol and HDL alone. This method requires a 9- to 12-hour fast. However, WISEWOMAN screenings may occur during a breast and cervical cancer-screening visit when women are unlikely to have fasted. Consequently, WISEWOMAN allows projects to determine cholesterol levels by using nonfasting total cholesterol and HDL-cholesterol testing. In such a case, if total cholesterol is ≥200 mg/dL or HDL is <40 mg/dL, a follow-up or diagnostic lipoprotein profile is needed for appropriate management based on LDL.

The full ATP III report can be accessed at www.nhlbi.nih.gov. See Appendix D for ATP III's Quick Desk Reference that provides ATP III lipid and lipoprotein classifications, specific steps for determining a patient's risk category, and specific

treatment recommendations based on LDL-cholesterol level. This resource also gives information on treating metabolic syndrome and elevated triglycerides.

Risk Factor: Elevated Blood Glucose

Although screening for elevated blood pressure and cholesterol is mandated by WISEWOMAN legislation, screening for diabetes is optional for projects.

The risk of developing type 2 diabetes increases with age, obesity, and lack of physical activity. These risk factors are not uncommon in the WISEWOMAN target population. WISEWOMAN projects are allowed to screen for diabetes by either using fasting plasma glucose (FPG) or taking a casual plasma glucose (nonfasting) measurement. The American Diabetes Association 2002 Clinical Practice Recommendations state that fasting plasma glucose (FPG) is the best screening test for diabetes because it is easier and faster to perform, more convenient and acceptable to patients, and less expensive. The oral glucose tolerance test (OGTT) may be necessary for the diagnosis of diabetes when the FPG is <126 mg/dL but diabetes is highly suspected.

Because many WISEWOMAN participants will visit their provider in a nonfasting state, WISEWOMAN does allow projects to use nonfasting blood glucose testing. The ADA refers to such tests as *casual* plasma glucose measurements, that is, the measurement is taken without regard to the time of the last meal. A casual plasma glucose level ≥200 mg/dL with symptoms of diabetes is considered diagnostic of diabetes. These symptoms include excessive thirst, blurred vision, frequent urination, and weight loss. A confirmatory FPG test or OGTT should be completed on a different day if the clinical condition of the patient permits. (Diabetes Care, Vol. 25, Supplement 1, January 2002, S21-24). Appendix E contains the American Diabetes Association 2002 Clinical Practice Recommendations.

Screening, Referral, Tracking, and Reporting Policy 4.4

Medical Referral for Women with Abnormal Values

A major responsibility of WISEWOMAN project staff is to ensure that women with abnormal screening values are referred to a health care provider for appropriate diagnostic examinations in accordance with national and program guidelines.

Projects will track information to determine the mean number of days from the screening visit to referral and the means days from the screening visit to the diagnostic visit. This information, which does not need to be submitted to CDC, is used by the project to detect problems with the referral systems.

In summary, projects will want to refer to JNC VI, ATP III, and ADA's recommendations as well as UNC's WISEWOMAN monograph entitled "Integrating Cardiovascular Disease Prevention into Existing Health Services" when they work with their health care advisory team to determine screening, referral, and management guidance for high blood pressure, blood cholesterol, and blood glucose. Numerous issues should be addressed with all health care providers:

- Training needs for providers regarding national clinical care recommendations on detection, evaluation, and treatment for high blood pressure, blood cholesterol, and blood glucose.
- Protocol that describes how to screen participants in accordance with national and program guidelines.
- WISEWOMAN requirement that two blood pressure measurements be reported as minimum data elements (MDEs).
- Classification of abnormal values and WISEWOMAN alert values.
- Outline of when and how health care providers will conduct follow-up care of WISEWOMAN participants with abnormal values to include care needed beyond the one screening and one diagnostic visit paid for annually by WISEWOMAN.
- Development of tracking and monitoring systems that assure that women receive the care they need.
- Assurance that women receive the pharmacological treatment needed.
- Management and documentation needed for women with alert values, in accordance with WISEWOMAN program.

- Description of the criteria and procedures for initiating the lifestyle intervention.
- Symptoms in place to identify major risk factors (exclusive of LDL cholesterol) that modify LDL goals: cigarette smoking; hypertension (BP ≥140/90 mm Hg or on antihypertensive medication); low HDL cholesterol (<40 mg/dL); family history of premature CHD (CHD in male first-degree relative aged <55 years; CHD in female first-degree relative aged <65 years); age (men ≥45 years, women ≥55 years); *HDL cholesterol ≥60 mg/dL counts as a "negative" risk factor, i.e., its presence removes one risk factor from the total count.*
- ATP III preference for screening is to use fasting lipid panel measurements. If this is not feasible, WISEWOMAN will reimburse for nonfasting total cholesterol and HDL levels.
- Determination of 10-year risk assessment using Framingham scoring guidance to identify individuals whose short-term (10-year) risk warrants consideration of intensive treatment.

Clinical Follow-up and Tracking Activities

Clinical follow-up is defined as all medical services provided to a woman—after baseline referral and before the annual rescreen—to address the results of baseline screening. These services include medical care and support services aimed at improving adherence to medical care and treatment.

Clinical tracking is defined as the analysis of client data to ensure that each woman enrolled in the program receives timely and appropriate rescreening, as well as diagnostic and treatment services. Programs will distinguish between the collection of client data primarily for the direct provision of screening, intervention, and follow-up services and data primarily for the purposes of program evaluation. As this definition implies, tracking data are distinguished from CDC program evaluation data (i.e., MDEs that include intervention process measures). See Chapter 8, Evaluation, for additional information about MDEs reported to CDC.

For WISEWOMAN, a tracking system should be developed to ensure that eligible NBCCEDP women are screened for WISEWOMAN services, that all screening test results are reported to the project, that women obtain medical referrals for needed diagnostic services, and that women return for their annual rescreen.

Annual Rescreens

All women who receive WISEWOMAN baseline screening will be reassessed annually. Although national guidelines may indicate that a woman with a normal value does need not to be rescreened 1 year later (normal blood pressure, 2 years; normal cholesterol, 5 years; normal glucose, 3 years), the WISEWOMAN program requires annual screening to help facilitate program evaluation.

Six-month Follow-up

This visit is an option available only to enhanced programs so that an additional 6-month measurement can improve the statistical power of their study. Only for enhanced projects can WISEWOMAN funds be used to pay for this visit and needed measurements.

Twelve-month Follow-up

Annual rescreens are mandatory for every participant regardless of baseline screening results. The same screening tests and risk factor assessments that were collected and reported at baseline are repeated and reported during each annual rescreening visit. These data are submitted as screening MDEs.

Referral criteria for high blood pressure, high blood cholesterol, and high blood glucose are the same as those used at baseline. If the client has met her blood pressure and blood cholesterol goals within 1 year, she still needs to return for annual rescreens for purposes of program evaluation. The same is true for other screening measurements, such as blood glucose, if applicable.

For participants who fail to achieve their blood pressure or blood cholesterol goal after 1 year, the lifestyle intervention may be repeated, or maintenance activities and/or a booster program may be offered. The same is true for blood glucose, if applicable.

Screening, Referral, Tracking, and Reporting Policy 4.5

Requirement for Annual Rescreens

A system is in place to track all WISEWOMAN participants, regardless of screening results, and to remind them to return for their annual rescreens. Annual rescreening consist of the same screening tests that were completed at baseline and will use the same health behaviour questions asked during the initial visit (these are reported as MDEs). A minimum of 75 percent of all women initially screened will return for at least one annual rescreen per CDC performance indicator standard.

women with alert values receive immediate or timely medical attention to reduce serious consequences. Chapter 3, Adherence to National Clinical Care Guidelines and Program Guidelines, contains background information on how the alert value measurements were selected.

Tracking a woman with an alert value involves documenting that she receives timely referral, diagnosis, and treatment services. Programs are expected to track the care of every woman with an alert value until she begins treatment. In addition, the WISEWOMAN project may learn about her progress when she returns for her annual rescreening office visit. Chapter 8, Evaluation, provides information on reporting alert values to CDC.

Screening, Referral, Tracking, and Reporting Policy 4.6

Medical Referral and Documentation of Women with Alert Values

Women with alert values are to be referred to a health care provider immediately or within 1 week, depending on the clinical situation, in accordance with national and program guidelines. Projects are encouraged to provide support services to women with alert values to ensure receipt of follow-up medical care and treatment. Documentation of referral and receipt of care and treatment for each woman with an alert value is reported to the CDC quarterly.

Chapter 5: Lifestyle Intervention

Background

Cardiovascular diseases are the leading cause of mortality among women of all major racial and ethnic groups in the United States. Approximately one in five women has some form of cardiovascular disease (CVD), and the risk of women dying from CVD is greater than the risk of the next 16 causes of death combined. Despite the high prevalence of cardiovascular disease, surveys reveal that women perceive their risk of getting breast cancer to be as high as their risk of developing CVD.

Obesity, physical inactivity, poor diet, and smoking are known to be modifiable risk factors for CVD and other chronic diseases. Modifying these risk factors through lifestyle intervention offers the potential to prevent disease and is proven effective in lowering cardiovascular disease risk factors at relatively little cost and with minimal risk. Participants should be strongly encouraged to adopt lifestyle modifications, particularly if they have risk factors for cardiovascular disease. Even when lifestyle modifications alone are not adequate in controlling risk factors, they may reduce the number and dosage of medications needed.

WISEWOMAN strongly encourages the use national guidelines for heart healthy eating, physical activity, and tobacco cessation to guide intervention development.

National Guideline Recommendations for Heart Healthy Diet

Both ATP III and JNC VI recommend the use of lifestyle interventions to reduce the risk of CVD. ATP III identifies modifiable life-habit risk factors that can be addressed through lifestyle interventions such as cigarette smoking, obesity, physical inactivity, and an atherogenic diet (a diet high in saturated fat and cholesterol leading to elevated LDL levels). ATP III recommends the initiation of therapeutic lifestyle changes (TLC) to achieve LDL cholesterol goals. Features of TLC are weight management, increased physical activity, and dietary modifications. The TLC diet encourages low intakes of saturated fat, trans fat, and cholesterol; selecting foods rich in complex carbohydrates and fiber, such as grains, especially whole grains, fruits, and vegetables; and balancing energy intake with expenditure to maintain desirable body weight or prevent weight gain. For more information about the TLC diet, see http://www.nhlbi.nih.gov/guidelines/ cholesterol/atp3_rpt.pdf.

JNC VI encourages the use of the Dietary Approaches to Stop Hypertension (DASH) eating plan, which is rich in vegetables, fruit, and low-fat dairy products

and is low in total and saturated fat. The DASH-Sodium trial found the diet along with sodium restriction to be beneficial for individuals with high blood pressure or those wishing to prevent high blood pressure. In addition, recent study findings provide evidence that individuals with high blood cholesterol can also benefit significantly from this eating plan. For more information about the DASH diet, see http://www.nhlbi.nih.gov/hbp/prevent/h_eating/h_eating.htm.

Counseling a woman to eat more vegetables and fruits, through the DASH eating plan or the 5 A Day program, may assist her in consuming a lower-fat and higher-fiber diet and thus support national guideline recommendations. WISEWOMAN encourages projects to incorporate these types of meal plans and messages into their interventions.

National Guideline Recommendations for Physical Activity

Lifestyle intervention counseling geared toward physical activity should support recommendations from the Surgeon General's Report on Physical Activity and Health (1996). This report states that for better health physical activity should be performed regularly. The recommendations advise people of all ages to include a minimum of 30 minutes of physical activity of moderate intensity (such as brisk walking) on most, if not all, days of the week. The report also acknowledges that for most people greater health benefits can be obtained by engaging in physical activity of more vigorous intensity or of longer duration. The report can be downloaded from http://www.cdc.gov/nccdphp/sgr/contents.htm.

National Guideline Recommendations to Treat Tobacco Use

Tobacco dependence is a chronic condition that often requires repeated intervention; however, effective treatment can produce long-term or even permanent abstinence. The Public Health Service (PHS) document entitled Treating Tobacco Use and Dependence: A Clinical Practice Guideline (2000) states that because effective tobacco dependence treatments are available, every patient who uses tobacco should be offered at least one of these treatments:

- Patients *willing* to try to quit tobacco use should be provided treatments identified as effective in this guideline.
- Patients *unwilling* to try to quit tobacco use should be provided a brief intervention designed to increase their motivation to quit.

There is a strong dose-response relation between the intensity of tobacco dependence counseling and its effectiveness. For additional information about

assisting women who want to quit smoking, see http://www.surgeongeneral.gov/tobacco/default.htm.

National Guideline Recommendations to Treat and Reduce Prevalence of Overweight and Obesity

In 1998 the National Heart, Lung, and Blood Institute (NHLBI), in cooperation with the National Institute of Diabetes and Digestive and Kidney Diseases, released the first federal guidelines on the identification, evaluation, and treatment of overweight and obesity. About 97 million adults in the United States are overweight or obese. Obesity and overweight substantially increase the risk of morbidity from hypertension, dyslipidemia, type 2 diabetes, coronary heart disease, stroke, gallbladder disease, osteoarthritis, sleep apnea and respiratory problems, and endometrial, breast, prostate, and colon cancers. Higher body weights are also associated with increases in all-cause mortality. See http://www.nhlbi.nih.gov/guidelines/obesity/ob_home.htm.

In addition, NHLBI has launched the Obesity Education Initiative (OEI) to encourage the adoption of heart-healthy eating patterns and physical activity habits. To learn more about their population-based strategies to manage overweight and obesity, as well as strategies to promote physical activity, see http://www.nhlbi.nih.gov/about/oei.

Diabetes Prevention Studies Provide Additional Support for Use of Lifestyle Interventions

Obesity and a sedentary lifestyle are known to increase the risk of type 2 diabetes. The US Diabetes Prevention Program (DPP) and the Finnish Diabetes Prevention Study both provide substantial evidence that type 2 diabetes can be prevented with lifestyle change. The DPP found that diet and exercise resulting in a 5 to 7 percent weight loss lowered the incidence of type 2 diabetes by 58 percent. Participants in this clinical trial received culturally sensitive training in diet, exercise, self-monitoring, goal setting, and problem-solving. Participants lost weight by cutting fat and calories in their diet and by exercising (most chose walking) at least 30 minutes a day, 5 days a week. The Finnish Diabetes Prevention Study also showed that diet and exercise could delay onset of type 2 diabetes in at-risk people. For more information on these studies, see www.hhs.gov/topics/diabetes.html.

Approval Requirement for Enhanced and Standard Projects

Enhanced Projects
WISEWOMAN enhanced projects are funded to use scientifically rigorous methods to test the effectiveness of a behavioral or lifestyle intervention aimed at preventing CVD. Enhanced projects must submit interventional plans in the form of a protocol for both CDC project officer approval and human subjects review. Enhanced projects are strongly encouraged to use the expertise of their state or local academic community or other academic communities already involved in WISEWOMAN projects.

Standard Projects
WISEWOMAN standard projects are funded to design culturally appropriate lifestyle interventions based upon scientific evidence that the proposed intervention has been effective in lowering blood pressure or cholesterol or improving physical activity or nutrition in a similar target population. Standard projects are encouraged to select an effective intervention, as stated above, or they can use a newly designed intervention if it incorporates sound theoretical principles of behavioral change, such as use of the socioecologic model to intervene at multiple levels, individual tailoring, self-efficacy, self-monitoring and reinforcement, readiness for change, small achievable steps, social support, collaborative goal setting, and strategies to overcome barriers.
WISEWOMAN encourages projects to use a systematic team approach involving health care professionals and paraprofessionals, community health workers, and community resources. A team is necessary to provide the needed education, follow-up, and support, and to sustain behavioral change. WISEWOMAN interventional plans should be detailed in a protocol developed during the planning phase and must be submitted to CDC project officers for approval before the start of screening and intervention.

Lifestyle Intervention Policy 5.1

Approval Requirement For Lifestyle Intervention

WISEWOMAN interventional plans should be detailed in a protocol developed during the planning phase and must be submitted to CDC project officers for approval before the start of screening and intervention. In addition, the CDC Institutional Review Board must approve an enhanced project's plans.

Selecting and Developing an Intervention

Literature reviews, theoretical foundations, and training courses can assist projects working to select and develop the appropriate lifestyle intervention.

Literature Reviews

A review of the literature was conducted by Wilcox and colleagues (2001) to identify effective nutrition and physical activity interventions that reduce CVD risk in health care settings with a focus on women. The authors determined the size of the effect of 32 interventions whose goal was to affect body mass index or weight, dietary fat, blood pressure, or total and low-density lipoprotein serum cholesterol. The more successful interventions were PACE (Patient-centered Assessment & Counseling for Exercise & Nutrition) and A New Leaf…Choices for Healthy Living. Both of these interventions are currently employed by WISEWOMAN projects. A copy of this literature review is in Appendix F.

The Women's Cardiovascular Health Network, whose members represent 10 Prevention Research Centers, also conducted a literature review. They identified 65 population-based studies that focused on improving women's CVH through behavioral change for tobacco use, physical inactivity, and diet. Although cardiovascular health interventions geared toward women are scant, the Network did identify effective program components. These include personalized advice on diet and physical activity behaviors and tobacco cessation, multiple staff contacts with skill building, daily self-monitoring, and combinations of strategies (Krummel et al., 2001). For more information about the Women's Cardiovascular Health Network, see http://www.hsc.wvu.edu/womens-cvh/

The Task Force on Community Preventive Services has recently issued recommendations for interventions to increase physical activity. Each recommendation is based on the strength of the evidence of effectiveness found during systematic reviews. Strongly recommended interventions include the following:

- Community-wide campaigns
- School-based physical education
- Social support interventions in community settings
- Individually adapted health behavioral change programs
- Creation of or enhanced access to places for physical activity combined with informational outreach activities

For more information on The Community Guide to Preventive Services, Increasing Physical Activity, see http://www.thecommunityguide.org.

Theoretical Foundations

The programs that are most likely to succeed are those based on a clear understanding of the targeted health behaviors and their environmental context. Theory can help programs during the various stages of planning, implementing, and evaluating an intervention. Program planners use theories to shape the pursuit of answers to WHY? WHAT? and HOW? That is, theories can be used to guide the search for reasons WHY people are or are not following public health and medical advice or are not caring for themselves in healthy ways. They can help pinpoint WHAT you need to know before developing or organizing an intervention program. They can provide insight into HOW you shape program strategies to reach people and organizations and have an impact on them. They also help you identify WHAT should be monitored, measured, and/or compared in the program evaluation (NCI, 1997)

The socio-ecological perspective provides a multileveled, interactive approach to help direct the identification of personal and environmental leverage points for health promotion interventions. Although all eligible WISEWOMAN participants are offered interventions that address individual problems, WISEWOMAN projects are also encouraged to work with their partners to address the various levels of influence identified through the socio-ecological perspective. Table 5.1 lists theories that can be used to address the different problem and intervention levels identified through the socio-ecological perspective.

Table 5.1 Socio-ecological Perspective

Problem and Intervention Level	Theories
Individual	• Theory of planned behavior • Transtheoretical model (stage of change) • Persuasion communication model • Goal-setting theory • Attribution theory • Health belief model • Self-regulation theories
Interpersonal	• Social cognitive theory • Diffusions of innovations theory • Social network and social support theories
Organization	• Stage theory of organizational change • Organizational development theory • Interorganizational relationship theory
Community	• Conscientization • Community organization
Society and Policy	• Agenda-building theory • Policy windows theory

Source: Intervention Mapping, 2001, p.80

For more information about theoretical foundations, see the National Cancer Institute's publication, Theory At A Glance, at http://oc.nci.nih.gov/services/Theory_at_glance/HOME.html

WISEWOMAN also provides training on behavioral change models and theories through the Nutrition and Public Health course.

Nutrition and Public Health: A Course for Community Practitioners
The WISEWOMAN-sponsored course on nutrition and public health provides technical assistance pertinent to the projects as they develop, implement, and evaluate their lifestyle intervention. This course was developed to serve the public health practitioner who works with populations with little or no access to health care services. The curriculum is designed for practitioners with limited experience in nutrition science or behavioral interventions. Emphasis is given to nutrition interventions for low-income and minority women at increased risk for chronic diseases associated with dietary and lifestyle practices (such as WISEWOMAN participants). Faculty with practical and/or academic expertise in public health approaches to healthy eating will teach individual, community, and

environmental/policy nutrition approaches to interventions. Topics for the course include

- Hot topics in nutrition science
- Socioecologic and public health practice models for nutrition promotion
- Needs and assets assessment—individual and community Intra- and inter-personal level behavioral change
- Organization and community influences on diet, and strategies for change
- Policies that affect dietary intake and their potential to influence change
- Program evaluation
- Plain language materials development for low-literacy, low-income, and culturally diverse audiences
- Examples of exemplary nutrition programs

Course attendance is mandatory for WISEWOMAN project staff, and it will be offered annually. WISEWOMAN funds are allocated for this course per Policy 2.2. Budget Requirements for Staff Development. For more information about the course, see http://www.hpdp.unc.edu/nph/.

Community Engagement

The CDC/ATSDR Committee for Community Engagement defines *community engagement* as the process of working collaboratively with and through groups of people affiliated by geographic proximity, special interest, or similar situations to address issues affecting the well-being of community members. Community involvement is a powerful vehicle that may bring about environmental and behavioral changes that improve the health of the community, including WISEWOMAN participants. It often involves partnerships and coalitions that help mobilize resources and influence systems, change relationships among partners, and serve as catalysts for changing policies, program, and practices.

Community engagement is important for WISEWOMAN projects. By engaging the community and developing partnerships, the WISEWOMAN project may facilitate the changes needed to bring about systematic change at multiple levels of society and thus sustain CVH-promoting efforts. To read more on this subject, you can access *Principles of Community Engagement* (CDC, 1997) at http://www.cdc.gov/phppo/pce/index.htm.

Maintenance or Relapse Prevention

Although intervention programs are intended to help individuals adopt positive dietary and physical activity behaviors, surprisingly few result in long-lasting change. Programs that do not achieve long-term behavioral change cannot be considered highly effective, nor do they make efficient use of health facility resources. The high rates of relapse that tend to occur after short-term behavioral interventions necessitate *maintenance* programs that promote long-term adherence to the new behavioral patterns. The UNC WISEWOMAN Manual (2001) states that well-designed maintenance programs do the following:

- Provide the participant with ongoing contact with health facility staff (either in person or by mail)
- Are cost-effective and time-efficient
- Involve the participant in collaborative planning (including goal-setting) and mutual development of a treatment plan
- Include relapse prevention strategies that incorporate reinforcement management, helping relationships, counter-conditioning, and stimulus control

Lifestyle Intervention Follow-up

Lifestyle intervention follow-up includes all services provided outside the formal intervention program for the purpose of promoting attendance at intervention sessions and adherence to lifestyle interventions. WISEWOMAN funds may be used to provide follow-up services to promote complete attendance. An example would be community health workers making follow-up calls that encourage women to meet their goals.

Lifestyle Intervention Policy 5.2

Lifestyle Intervention Follow-up

WISEWOMAN funds may be used to provide follow-up services to promote complete attendance at and adherence to a project's standardized intervention program. To meet the CDC performance standard, 75 percent of eligible women must attend at least one intervention and 60 percent must complete all intervention sessions.

Lifestyle Intervention Tracking

Projects will develop a system that allows for the analysis of participant data to ensure that a woman enrolled in the intervention receives the complete intervention program. Participant-level data will be reported to CDC or a contractor for program evaluation twice a year, along with other MDE submissions. The intervention process measures include the date of the session attended and the type of intervention session (e.g., nutrition, physical activity, tobacco, or a combination). Projects are encouraged to use these data to look for barriers and to implement strategies that overcome identified barriers.

CDC will use this information to determine the intervention exposure and whether completion of the interventional activities occurred in a timely manner. For additional information, see Chapter 7 on Program Protocols and Chapter 8 on Evaluation.

Lifestyle Intervention Policy 5.3

Tracking Participation of Lifestyle Intervention

Projects will develop a system for analysis of participant data, first, to ensure that a woman enrolled in the intervention receives the complete interventional program in a timely manner and, second, to assist in program evaluation.

Links to Additional Resources

Fruit and Vegetable Links

CDC and Five A Day
http://www.cdc.gov/nccdphp/dnpa/5ADay/index.htm

National Cancer Institute 5 A Day
http://www.5aday.gov/

Produce for Better Health Foundation, 5 A Day*
http://www.5aday.org/

Dole Food Company, 5 A Day
http://www.dole5aday.com

DASH – Dietary Approaches to Stop Hypertension

http://www.nhlbi.nih.gov/hbp/prevent/h_eating/h_eating.htm

Physical Activity Links

CDC's Division of Nutrition and Physical Activity's Physical Activity Topics
http://www.cdc.gov/nccdphp/dnpa/physicalactivity.htm

The Community Guide to Preventive Services, Increasing Physical Activity
http://www.thecommunityguide.org.

National Blueprint: Increasing Physical Activity Among Adults Age 50 and Older
http://www.cdc.gov/nccdphp/dnpa/physical/lifestyles.htm

The Effectiveness of Interventions to Increase Physical Activity. Kahn EB, Ramsey LT, Brownson R, Heath GW, Howze EH, Powell KE, Stone EJ, Rajab MW, Corso P, Task Force on Community Preventive Services. Am J Prev Med. 2002: 22 (4S); 73-107.

* Links to nonfederal organizations found in this chapter and document are provided solely as a service to our users. These links do not constitute an endorsement of these organizations or their programs by CDC or the Federal Government, and none should be inferred. The CDC is not responsible for the content of the individual organizations' Web pages found at these links.

Chapter 6: Medication

Background

The legislative provisions for WISEWOMAN, contained in the Breast and Cervical Cancer Mortality Prevention Act of 1990 (Public Law 101-354), do not allow resources appropriated for the program to be used for treatment. WISEWOMAN Legislative Requirement Policy 1.4 states that WISEWOMAN funds cannot be used for any treatment, including medications.

As of October 2000 states have the option to provide medical assistance through Medicaid to eligible women who were screened for and found to have breast or cervical cancer, including precancerous conditions, through NBCCEDP (Public Law 106-354). A similar Act does not exist for chronic diseases such as cardiovascular disease. Therefore, projects should work with their health care providers to ensure that participants who need it have access to low-cost or free medication.

Ensuring Access to Medication

The RFA for WISEWOMAN asks successful applicants to develop a system to ensure access to medications for women who require this augmentation to behavioral or lifestyle intervention. This system should be described in the Appropriate Linkages to Medical Care Protocol that is required to be submitted by projects during their planning phase (see protocols section in Chapter 7). Protocols for medication access must be approved by a CDC/WISEWOMAN project officer before screening and intervention can begin. Table 6.1 provides a list of resources and links that may assist projects and providers in ensuring eligible women's access to free or low-cost medications.

Medication Policy 6.1

Ensuring Access to Medication

A system to ensure access to medications must be described in a protocol that is approved by a CDC project officer before the start of screening and intervention.

Table 6.1 Links to Patient and Physician Resources for Discounted and Free Medication*

Resource	Description	Contact Information
340B Drug Discount Program	HRSA's program under which certain federally funded grantees have access to low-cost pharmaceutical drugs.	http://bphc.hrsa.gov/opa/
Cost Containment Research Institute	Sells $5.00 booklet describing pharmaceutical companies/indigent patient programs	www.institute-dc.org
MySimon Prescription Drugs	Compares the prices of pharmaceutical products listed on the Web.	www.mysimon.com/category/index.jhtml?c=prescriptiondrugs
PhRMA Directory of Patient Assistance Programs	Directory of PhRMA members who assure access to medicines to those who cannot afford to purchase them.	http://www.phrma.org/searchcures/dpdpap/
Rx Assist and Rx Assist Plus	Developed by Volunteers in Health Care, a program of the Robert Wood Johnson Foundation, RxAssist provides physicians and other health care providers with the information they need to access programs that offer a limited supply of free or low-cost medications. Rx Assist Plus is free patient and medication tracking software. Application forms for programs are also available.	http://www.rxassist.org/default.cfm
Rx Hope	A free program that helps physician offices apply for, obtain, and track requests for no-cost medications offered by federal, state, and charitable organizations.	http://www.rxhope.com/
State Pharmaceutical Assistance	Identifies states that have established or authorized some type of program to provide	http://www.ncsl.org/programs/health/drugaid.htm

Programs	pharmaceutical coverage or assistance, primarily to the low-income elderly or persons with disabilities who do not qualify for Medicaid.	
The Medicine Program	Assists patients in applying to pharmaceutical companies' indigent patient programs	www.themedicineprogram.com

* Links to nonfederal organizations found in this chapter and document are provided solely as a service to our users. These links do not constitute an endorsement of these organizations or their programs by CDC or the Federal Government, and none should be inferred. The CDC is not responsible for the content of the individual organizations' Web pages found at these links.

Chapter 7: Program Protocols

Background

WISEWOMAN protocols provide a road map or orientation for all employees and contract providers. Development of and adherence to protocols by staff are crucial to the integrity of the program. All protocols should incorporate national guidelines, as appropriate.

Protocol Development

Projects should involve health care providers, supervisors, community health workers, interventionists, and even participants, as appropriate, in protocol development. Development involving key stakeholders will not only result in the creation of relevant protocols, but it may also gain buy in or support of protocols at multiple levels. Plans are needed to assure that all WISEWOMAN staff and providers review protocols and receive appropriate training to increase adherence to protocols.

WISEWOMAN anticipates that protocols will continually evolve as the program is refined through feedback and evaluation. Project and CDC staff should review protocols at least annually. CDC project officers will use protocols to assist in the determination of how thoroughly recipient activities are planned and carried out.

Program Protocols 7.1

Protocol Requirements

Projects must develop protocols that contain detailed descriptions of WISEWOMAN activities. The CDC project officer must approve protocols before a project initiates screening or intervention activities.

WISEWOMAN Program Start-up Checklist

The WISEWOMAN manual, *Integrating Cardiovascular Disease Prevention into Existing Health Services: The Experience of the North Carolina WISEWOMAN Program* (UNC, 2001), is a useful resource for assisting projects in overall, as well as protocol, development of their WISEWOMAN program. The manual was developed by The Center for Health Promotion and Disease Prevention of the University of North Carolina at Chapel Hill as a "how to" guide for developing an integrated CVD screening, intervention, and evaluation program for low-income and/or uninsured women. It contains the North Carolina WISEWOMAN Program

Start-up Checklist (p. 18, 2001). WISEWOMAN projects are strongly encouraged to use this checklist as they identify the tasks needed to develop and implement a WISEWOMAN program. A generic version of this checklist is in Appendix G. Besides this checklist, there is a CDC-developed, comprehensive list of protocol elements. CDC project officers will use the following list of protocol elements to determine project readiness to initiate screening and intervention activities.

Screening Protocol Elements

1. Recruitment (using inreach or outreach strategies). Determine who will do the recruiting for WISEWOMAN services and how this recruitment will occur. Describe recruitment training efforts and strategies that maximize participation in WISEWOMAN screening services. Describe procedures that notify the provider when a woman is eligible for WISEWOMAN services.
2. Laboratory Standards. Adhere to all applicable requirements established under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). Ensure precise and accurate cholesterol measurements and meet the standards defined by the Laboratory Standardization Panel of the NCEP.
3. Oral and Printed Communication of Screening Results. Describe how interpretation of test results will be reliably communicated to the participant orally and in writing. For an example of a letter to participants regarding baseline screening results, see page A-17 in the WISEWOMAN manual at http://www.hpdp.unc.edu/wisewoman/.
4. Training and National Guidelines. Ensure that staff members have training specific to their responsibilities, access to consultation from appropriate health professionals, and adequate supervision. Describe how providers will follow NCEP and JNC VI screening guidelines. Describe how projects will monitor providers' adherence to guidelines.
5. Screening Site Selection. Describe how sites are selected for WISEWOMAN screening. WISEWOMAN recommends utilizing "strong" BCCEDP sites: those that can offer comprehensive services, are convenient, serve an adequate number of women, incorporate quality control procedures, and ensure privacy.
6. Formalized Commitments. Describe methods used to assure that all federal and state WISEWOMAN program protocols are followed, including letters of cooperation or other formal agreements.
7. Screening Costs. Describe which screening tests will be performed and the reimbursement rates for each test or procedure. Submit a current list of CPT codes that the project intends to use. WISEWOMAN strongly

encourages projects to use WISEWOMAN funds to pay 100 percent of the Medicare-allowable charge (i.e., WISEWOMAN clients should not have any out-of-pocket expenses).

8. Community Support. Describe partnerships at state and local levels including community networks, partnering with local community health organizations, and grassroots efforts to increase awareness of CVD risk factors in women and extend services to reduce CVD risk factors

9. Referrals and Follow-up. Describe the screening agency's clinical referral and follow-up system to ensure that women with abnormal results obtain medical care in accordance with national guidelines. Desirable follow-up methods include letters or telephone calls.

10. Annual Rescreenings. Describe how women will be reminded about their annual rescreening visits. For evaluation purposes, women are to be rescreened annually for as long as they are enrolled in the program. Rescreening occurs 12 months (+/- 2 months) after the initial screening. The same screening tests and behavior or health risk appraisal questions conducted at the initial screening visit are repeated at each annual rescreening visit.

11. Tracking and Monitoring. Describe a tracking system that will be used to assure that women will receive timely and appropriate rescreening and evaluation, diagnostic services when needed, and subsequent treatment services.

12. Women Who Have Alert Values. Describe the system for referral and care of women with alert values. Include a description of procedures for notifying the participant of her alert and/or abnormal values. Provide a summary report of women with alert values in the quarterly progress report.

13. Consent Form. Develop a consent form that meets IRB clearance. See "Integrating Cardiovascular Disease Prevention into Existing Health Services: The Experience of the North Carolina WISEWOMAN Program" for a sample consent form appropriate for standard projects. Enhanced projects should work with their project officer to develop their consent form and protocol. CDC's website for Human Subject Research also contains information about consent forms at http://www.cdc.gov/od/ads/hsr2.htm.

14. Promote Intervention. Describe how the screening agency will encourage eligible women to participate in intervention activities.

15. Data Reporting System. Describe the proposed system for data collection and reporting of MDEs, including samples of developed forms.

16. Adverse Event Report. Describe the proposed system for reporting adverse events from clinic to the state and from the state to the CDC. See the sample adverse event report form in Appendix I.

Lifestyle Intervention Protocol Elements

Projects are to address the following elements in their lifestyle intervention protocol.

1. Intervention Selection. Describe and provide rationale for the selected intervention. Describe the theoretical foundation that was used to guide the development of the intervention. Provide the CDC project officer with reference citations, if available.
2. Intervention Strategies That Support National Guidelines. Describe the type of nutrition and physical activity strategies that will be used in the intervention (e.g., incorporating therapeutic lifestyle changes as described in ATP III, or promoting the DASH eating plan as described in JNC VI, etc.). Strategies should be based on national guidelines, and the project should provide evidence of their success with the intended population.
3. Intervention Counseling and Setting. Describe how and where the intervention counseling will occur. That is, will the counseling be one-on-one or in a group setting, face-to-face or over the phone, at the screening provider's site or out in the community, provided by a nutritionist/health educator or community health worker, etc? Include a description of the topics covered during each session, the length of the session, and how assessments and individualized goal setting will occur.
4. Intervention Process Measures. Describe the system for collecting and reporting participant-level information about the number and type of sessions attended (i.e., interventional MDEs). Include a sample of forms developed. This information will be used to determine the exposure to intervention and whether completion of the interventional activities was timely.
5. Intervention Follow-up. Describe all coordination efforts that are available to maximize intervention attendance. Include plans for overcoming barriers that prevent women from participating in interventional activities.

Linkage to Medical Care Services and Other Protocol Elements

Projects are to address the following elements in their protocol to describe how they will link clients to appropriate, quality, and affordable medical care.

1. Contract Essentials. The following information is required by PGO for all new contracts: (1) name of contractor, (2) method of selection, (3) period of performance, (4) scope of work, (5) method of accountability, and (6) an itemized budget with justification for each line item. Requests to continue a previously approved contract should include an itemized budget with justification. A copy of a provider contract is required with the application.
2. Clinical Follow-up. Describe who is responsible for contacting patients who need additional medical care, such as a diagnostic exam. Describe who will send reminder notices, coordinate transportation if needed, etc. Describe how documentation from the health care provider will be submitted to the program. Describe if and how periodic audits will occur to assure that women receive follow-up care and medications, if applicable.
3. Provider Assurances. Describe the plan to assure that providers will follow national and WISEWOMAN guidelines. Refer to Chapter 3, Adherence to Guidelines, for additional information.
4. Access to Medication. Describe how the program will assure that providers will assist participants who need medication, including providing access to any sliding scale fees, discounted drug programs, or available indigent drug program.
5. Local Collaboration. Describe all collaborative efforts: include a list of state and local level partners, the frequency of meeting, a plan for supplementing existing services, and a plan for raising awareness in the community about WISEWOMAN screening and intervention activities. Collaborative efforts will increase the likelihood of the program's sustainability.
6. Partnerships. Describe relationships with traditional and nontraditional partners, including the state's Primary Care Association, American Heart Association, pharmaceutical organizations, state universities, and prevention research centers. In addition, describe the relationship the project has with state nutritionists, 5 A Day coordinators, physical activity interventionists, community health workers, chronic disease prevention programs (cardiovascular disease, diabetes mellitus, etc.), and offices of women's and minority health.

7. Quality Assurance and Improvement. Describe monitoring activities included in the quality assurance plan. Quality assurance and improvement entails the use of established standards, systems, policies, and procedures to monitor, assess, and identify practical methods for improvement. The purpose of the quality assurance plan is to ensure high standards of services delivered through the WISEWOMAN program.
8. Public Education and Outreach. Describe the public education activities that will be designed to deliver a clear, consistent message about the need for CVD and other chronic disease screening and lifestyle interventions. Describe the outreach plan with a variety of methods and strategies to reach WISEWOMAN priority populations and to encourage enrollment in the WISEWOMAN activities.

Be sure to include samples of all developed or draft forms with submission of the protocol.

Chapter 8: Evaluation

Background

Evaluating WISEWOMAN projects is important for several reasons. Evaluation can help document a project's successes, and it can identify program components that either work well or require modification. Evaluation strategies can be grouped into two broad categories:

1. Evaluations designed to determine a project's effectiveness and cost-effectiveness (i.e., does the program lead to reductions in risk factors and/or promote healthy behaviors?)
2. Evaluations designed to assess a project's operational approaches (i.e., can a CVD prevention education program be delivered to at-risk women attending a cancer screening program?)

Evaluation Questions: Program Effectiveness and Government Performance and Results Act

The Government Performance and Results Act (GPRA), established in 1993, requires that every major federal agency ask some very basic questions: What is our mission? What are our goals and how will we achieve them? How can we measure our performance? How will we use that information to make improvements? These questions have been addressed throughout this document. Furthermore, we have identified the following three GPRA measures by which our progress will be assessed and reported annually to Congress.

Goal 1: To improve access to preventive health services, including screenings for blood pressure and cholesterol, and health education for uninsured women aged 40–64 years participating in the National Breast and Cervical Cancer Early Detection Program.

Goal 2: To identify WISEWOMAN participants who are newly detected with high blood pressure or high cholesterol as a result of the WISEWOMAN program.

Goal 3: To increase the number of newly enrolled WISEWOMAN participants who adopt a healthier lifestyle during the first year after their enrollment.

To provide further information related to the third question, *enhanced* WISEWOMAN projects use scientifically rigorous methods to test the effectiveness and cost-effectiveness of a behavioral or lifestyle intervention that is grounded in the social and cultural context of the target population and aimed at preventing CVD.

Program Feasibility

Feasibility can be simply described as determining whether a CVD prevention education program can be delivered to at-risk women attending a cancer screening program and, if so, at what cost. A major goal of the *standard* WISEWOMAN project is to evaluate the effectiveness of operational approaches to conduct the following activities for women aged 40–64 years who participate in NBCCEDP: outreach, screenings for blood pressure, cholesterol, poor nutrition, physical inactivity, smoking, and other conditions (when appropriate), referral, lifestyle intervention, tracking and follow-up, evaluation, professional and public education, and community engagement.

The WISEWOMAN program has developed specific feasibility questions:

1. Is the targeted number of BCCEDP women served by the WISEWOMAN program?

2. Is there a substantial number of BCCEDP women who are at-risk for CVD? In other words, what is the burden of CVD risk factors and estimated 10-year CVD risk?

3. Does a substantial number of BCCEDP women engage in unhealthy behaviors (physical inactivity, smoking, poor eating habits)? In other words, is this an appropriate population for intervention?

4. What is the impact of the WISEWOMAN program on detection of at-risk women who were previously unaware of their at-risk status?

5. Assuming that all women can benefit from lifestyle improvements, are WISEWOMAN clients participating in lifestyle interventions and, if so, to what extent?

6. Are women who need CVD medications receiving them as a result of program participation?

7. Are the WISEWOMAN projects cost-effective?

Semiannual Reporting of Data to CDC: Minimum Data Elements

Minimum data elements (MDEs) are a set of standardized data elements developed to ensure that consistent and complete information on CVD risk factors and health behaviors are collected on women screened and diagnosed with WISEWOMAN funds. For a complete list of screening and intervention MDEs, please see Appendix I.

Evaluation Policy 8.1

Minimum Data Elements and Cost Data Reporting

Projects should collect and report minimum data elements and cost information in the format suggested by CDC to CDC or its contractor twice a year.

Report on April 15	Covering Dates through December 31
Report on October 15	Covering Dates through June 30

Projects should collect and submit MDE data to CDC or contractor on a semiannual basis. To avoid duplication, some of the MDEs such as demographic variables are taken directly from the NBCCEDP data collection systems. Other MDEs have been developed with input from WISEWOMAN projects specifically for the WISEWOMAN program. The health behavior data elements are project-specific because they are tied to the intervention design, which may vary across projects. However, they are considered standard elements because they are standardized across time for each project. The MDEs and cost data collected from projects are used to determine the effectiveness and feasibility of the WISEWOMAN program.

Semiannual Reporting of Data to CDC: Cost Data

The WISEWOMAN program, like all other federal government programs, is held accountable for the fiscal management of its resources. To determine cost effectiveness, all WISEWOMAN costs will be allocated to one of four WISEWOMAN-related activities. This information will be collected and submitted to the CDC designee for analysis on a bi-annual basis.

Outreach and follow-up. Activities that include reaching women for the purpose of enrolling them in the program and maintaining contact with them throughout the period of funding for annual rescreenings.

Screening. Activities that collect medical information about the participants. These activities include taking blood samples for glucose and cholesterol tests, measuring blood pressure, support services, and providing a professional assessment of the individual's health profile.

Intervention. Activities concentrating on improving the participants' awareness of cardiovascular disease risk factors. Counseling sessions, cooking classes, and physical activity classes are examples.

Administrative. Activities required to coordinate the program. This category includes all WISEWOMAN costs not captured in the categories above.

Additionally, costs will be subdivided at the site level into labor, materials and supplies, and contracted costs. The CDC contractor/designee and project officer will work with each project to develop a methodology to capture this information.

Quarterly Progress Reporting to CDC

In addition to reporting MDEs and cost data on a semiannual basis, projects are asked to submit information obtained from the tracking system to CDC quarterly. This information is used to communicate progress and issues to CDC, and CDC in turn uses the reports to answer congressional and other inquiries. The WISEWOMAN project coordinator submits the report to the CDC grants management specialist in the Procurements and Grants Office (PGO). A copy should also be sent to the CDC WISEWOMAN project officer as a courtesy. See Appendix J for the format suggested by CDC for quarterly reporting.

Evaluation Policy 8.2

Quarterly Progress Reports
Quarterly progress reports are due 30 days after the reporting period, as follows:

October 31	Covering Dates of July 1 – September 30
January 31	Covering Dates of October 1 – December 31
April 30	Covering Dates of January 1 – March 31
July 31	Covering Dates of April 1 – June 30

CDC Performance Indicators

CDC has developed performance indicators that allow projects to conduct continuous monitoring of progress using a CDC standard. CDC has based its performance indicators on phase one results of the Massachusetts and North Carolina WISEWOMAN projects. Demonstration projects will help determine future performance indicators and standards as program evaluation occurs. These indicators can also be found in Table 3 in the suggested format for quarterly progress reporting (Appendix K).

INDICATOR	CDC STANDARD
Number of NBCCEDP women eligible for WISEWOMAN services (aged 40-64 y) who are enrolled in WISEWOMAN	2500 women per year
Percentage of women screened who receive reliable oral and printed information about screening results and brief risk-reduction counseling	100%
Percentage lost to clinical follow-up	≤5%
Percentage of women who have abnormal values who receive referral for lifestyle intervention	100%
Percentage of WISEWOMAN (screened) who participate in at least one lifestyle intervention session	≥75%
Percentage of WISEWOMAN (screened) who complete all intervention sessions	≥60%
Percentage of WISEWOMAN (screened) who return for at least one annual rescreen	≥75%

Project Evaluation

Both standard and enhanced projects submit an evaluation plan to CDC. The plan should identify project-specific goals, objectives, and outcomes; specify tasks, methods, and procedures to be employed by whom, for whom, and over what period; and describe which data sources will be used and what resources will be allocated to achieve the objectives. Enhanced projects will work with a prevention research center or university partner to develop their evaluation design.

Projects should also establish acceptability objectives to determine the satisfaction with and acceptability of the program among health facility staff and program participants. To maintain or increase acceptability, projects will need to identify barriers to participation and satisfaction. To develop acceptability objectives, projects are encouraged to refer to the UNC WISEWOMAN manual for guidance: www.hpdp.unc.edu/wisewoman/.

Other evaluations might include assessments for increases in partnerships as a result of the project, improvements in medical care, the usefulness of community health workers in the project, increases in neighborhood assets, increases in knowledge of providers, improvements in participants' self-efficacy, and so forth. This information may be collected through various methods such as surveys, success stories, in-depth interviews, observation, chart reviews, and focus groups.

In summary, all stakeholders should be considered when developing an evaluation plan. Information and data related to GPRA goals, MDEs, cost data, and performance indicators have been identified to be of value to CDC. The information needs of other stakeholders, such as providers, legislators, interventionists, participants, and others should also be garnered when developing the evaluation plan.

References

Committee Report - House Rpt. 106–1033 – Making Omnibus Consolidated and Emergency Supplemental Appropriations for Fiscal Year 2001 (HR 196-1033, 2001)

Clinical Practice Recommendations. Diabetes Care. 2002;25(suppl 1):S21-24. http://care.diabetesjournals.org/content/vol25/suppl_1/

Joint National Committee. The Sixth Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. NIH Pub. No. 98-4080. Bethesda, MD: National Heart, Lung, and Blood Institute, 1997:70 pages. http://www.nhlbi.nih.gov/guidelines/hypertension/jnc6.pdf

HHS. Report of the US Preventive Services Task Force: Guide to Clinical Preventive Services, 2nd ed. Washington, DC: Government Printing Office, 1996.

Krummel DA, Matson Koffman D, Bronner Y, Davis J, Greenlund K, Tessaro I, Upson D, Wilbur J. Cardiovascular Health Interventions in Women: What Works? Journal of Women's Health & Gender-based Medicine. 2001;10:117-136.

NBCCEDP. National Breast and Cervical Cancer Early Detection Program Policies & Procedures Manual. Atlanta, GA: Centers for Disease Control and Prevention, 2000

National Cholesterol Education Program. Report of the Expert Panel on Population Strategies for Blood Cholesterol Reduction. NIH Pub. No. 90-3046. Bethesda, MD: National Heart, Lung, and Blood Institute, 1990:130 pages. http://rover2.nhlbi.nih.gov/guidelines/cholesterol/index.htm

NCI. Theory at a Glance: A Guide for Health Promotion Practice. 1997. http://oc.nci.nih.gov/services/Theory_at_glance/HOME.html

National Institutes of Health. Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults–The Evidence Report. NIH Pub. No.98-4083. Bethesda, MD: National Heart, Lung and Blood Institute, 1998a:262 pages. http://www.nhlbi.nih.gov/guidelines/obesity/ob_home.htm

Public Health Service. Treating Tobacco Use and Dependence: A Systems Approach. Clinical Practice Guideline. US Department of Health and Human Services, June 2000.

Title 42. The Public Health and Welfare, Chapter 61. The Public Health Service Preventive Health Measures with Respect to Breast and Cervical Cancers 42 U.S.C. § 300k (1996) http://www.cdc.gov/cancer/nbccedp/bccpdfs/uscodebc.pdf

US Department of Health and Human Services. Physical Activity and Health: A Report of the Surgeon General. Atlanta, GA: US Department of Health and Human Services, Public Health Service, CDC, National Center for Chronic Disease Prevention and Health Promotion, 1996.

University of North Carolina's Center for Health Promotion and Disease Prevention. Integrating Cardiovascular Disease Prevention into Existing Health Services: The Experience of the North Carolina WISEWOMAN Program. Center for Health Promotion and Disease Prevention, The University of North Carolina at Chapel Hill, 2001. www.hpdp.unc.edu/wisewoman/

Wilcox S, Parra-Medina D, Thompson-Robinson M, Will J. Nutrition and Physical Activity Interventions to Reduce Cardiovascular Disease Risk in Health Care Settings: A Quantitative Review with a Focus on Women. Nutrition Review. 2001; 59(7):197-214.

Appendixes

Appendix A: Policy Development Framework for the WISEWOMAN Program

Policy Development Framework for the WISEWOMAN Program

Steps in Policy Development

Step 1	Summarize existing policies
Step 2	Routinely solicit input for new policy areas
Step 3	Select a policy topic through a systematic process
Step 4	Select a panel of stakeholders to develop the policy
Step 5	Define the purpose and scope of the proposed policy
Step 6	Collect and synthesize information, options, scientific evidence as needed
Step 7	Devise a method to deliberate and to make judgments and recommendations
Step 8	Write, edit, and format the policy for review
Step 9	Provide for peer review and legal review
Step 10	Prepare final policy for dissemination
Step 11	Disseminate policy in policy and procedure manual
Step 12	Maintain a system for periodic review and updates as needed

WISEWOMAN's Definition of Policy A definite course or method of action selected from among alternatives and in light of given conditions to guide and determine present and future decision. (Source: Webster's Dictionary.)

Step 1	**Summarize existing policies** Before the need for new policies can be determined, existing policies must be identified and reviewed. Users of the policies will have easy access to existing policies, e.g., by electronic access to a policy and guidance manual. CDC will determine whether any existing policies are not being used or followed.
Step 2	**Routinely solicit input for new policy areas** The need for new policies is routinely assessed through a systematic process, such as annual surveys to program directors/coordinators, focus groups of program directors/coordinators, or other means. New policy areas will emerge throughout the life of the program for various reasons: - New technologies become available and projects need to know CDC's policy on use of a new technology, particularly under the terms of the cooperative agreement. - Policies affecting CDC may have a ripple-down effect, requiring some new action by projects to meet a new requirement imposed on CDC. - Controversies (a clash of opposing views) emerge among projects that can benefit from a systematic process to create a written policy. In addition to routine assessment of policy needs, CDC and projects can both propose policy area needs at any time during the year.

	For example, a project may submit policy suggestion to an identified CDC staff person via e-mail. The process used to determine policy needs will be documented. See Step 10.
Step 3	**Select a policy topic through a systematic process** Not all potential policy areas will require formal policies. Criteria for policy area selection include: - Change in legislative requirements - National guideline updates - Project/practitioner need or request for policy - Variation in existing practice (if all projects are already identical in their actions, a policy may not be needed) - Potential impact on morbidity, mortality, and quality of life - The cost, time, and resources for developing a policy is weighed against the anticipated benefits of a new policy - Areas of controversy, including adoption of new technologies, may present special cases for which federal-level policy is useful. All policies will support the mission of CDC, DNPA, and WISEWOMAN. The process used for policy selection will be documented. See Step 10.
Step 4	**Identify policy development panelists** Methodology will allow for fair and balanced project representation on the policy development panel. Objectivity and expertise are desired attributes of panel members. The panel composition will

	seek multidisciplinary and multicultural representation. Some policies may require consultation with CDC's Office of the General Counsel. Core members of the policy development include: - WISEWOMAN Team (all CDC project officers and team leader) - DNPA OD representative - All project coordinators and directors and other project representatives, as appropriate to the topic Depending on the policy topic, council from experts such as the consultant group and/or within CDC may be solicited. For example, programs implementing policies related to CVH may request guidance from the Division of Adult and Community Health (DACH), and those with policies related to diabetes may request guidance from Division of Diabetes Translation (DDT), etc. The composition of the policy development panel will be documented. See Step 10.
Step 5	**Define the purpose and scope of the policy** The intended audience for the policy will be made clear. Language in the policy will distinguish between *promising practices,* which may be recommended, and program requirements. The purpose and scope of the policy will be documented. See Step 10.
Step 6	**Collection and synthesis of information, options, scientific evidence, as needed** In technical areas, scientific or medical evidence may be needed for consideration by the policy panel. Criteria for assessment of evidence will be established on a case-by-case basis. For example, the US Preventive Services Task Force Evidence Guidelines provide clear and systematic guidelines to determine what literature is

	included in literature reviews and how this evidence is weighted in developing recommendations. As noted in Step 4, subject matter experts may also be consulted. In nontechnical areas, relevant information will be collected and synthesized. Viable options should be explored. The process used for collecting and synthesizing information will be documented. See Step 10.
Step 7	**Method used to deliberate, make judgments and recommendations** The preferred method for policy discussions is to convene the policy panel in conjunction with the scheduled annual WISEWOMAN project consultant meeting, as needed. Group interaction methods will be used to facilitate a productive meeting. CDC will consider advisement from the panel. If time does not allow for this, a teleconference will be arranged. The process used to facilitate group deliberations and decision-making will be documented. See Step 10. CDC makes all final policy determinations.
Step 8	**Write, edit and format the policy for review** CDC staff will write the policy and use language matched to the intended audience, subject matter, intention of the policy, and the dissemination vehicle.
Step 9	**Provide for peer review and legal review** If appropriate, the proposed policy may undergo legal review by CDC's Office of General Counsel. Proposed policies will be reviewed by the following stakeholders: - All project coordinators and directors - CDC WISEWOMAN Team

	- DNPA OD - National Breast and Cervical Cancer Early Detection Program - Internal Medical Advisors (Dr. Serdula, Dr. Dietz, Dr. Mensah, Dr. Vinicor, Dr. Lee), as needed - Legislative advisors, as needed A 45-day comment period will be allowed. Comments received from reviewers will be considered and the policy revised as appropriate. The process of soliciting the reviews and responses will be documented. See Step 10.
Step 10	**Prepare final policy for dissemination** The background information for the policy may state the following: - to whom the policy applies - the problem it addresses (or the reason the policy was developed) - a clear and explicit description of what is being recommended - evidence to support the recommended course of action (e.g., scientific evidence of effectiveness of a new technology). - when the policy goes into effect (and when it expires) - what degree of implementation is expected from programs - to the extent known, the expected costs and benefits of following the course of action recommended - the performance measures associated with this policy - what policy development methods were used - who participated in creation of the policy

	- contact information Pertinent documentation noted for Steps 2–9 will be included in the background section for each policy.
Step 11	**Dissemination policy** The WISEWOMAN Guidance Document will be updated to reflect new policies. Each new policy will be disseminated to WISEWOMAN coordinators, program directors, and program staff. In addition, policies relevant to other programs such as Breast and Cervical Cancer Early Detection Program staff will be disseminated to appropriate staff. A hard copy of the policy will be sent to each project coordinator/director and an electronic version will be made.
Step 12	**Maintain a system for periodic review and updates as needed** The WISEWOMAN Guidance Document will be reviewed annually by the CDC WISEWOMAN team.

Procedures for Fast Track Policy Development

There may be times when a new policy must be developed, reviewed, and disseminated expediently in response to a time-sensitive request. To accommodate such time constraints, CDC will develop the policy through a fast track process.

To fast track a policy, the following steps will be completed or omitted, as indicated below.

STEP	COMPLETE	OMIT
1. Summarize existing policies	Done	
2. Routinely solicit input for new policy areas		X
3. Select a policy topic through a systematic process		X
4. Identify policy development panelists		X
5. Define the purpose and scope of the policy	X	
6. Collect and synthesize information, options, and scientific evidence	X	
7. Method used to deliberate, make judgments and recommendations	Expedite	
8. Write, edit, and format the policy for review	X	
9. Provide for peer review and legal review	Expedite	
10. Prepare final policy for dissemination	X	
11. Disseminate policy	X	

Appendix B: Definition of Key WISEWOMAN Terms

DEFINITION OF KEY WISEWOMAN TERMS

Abnormal Values

Abnormal screening values for the WISEWOMAN program are the same as those listed in national clinical care guidelines. If a participant has an abnormal screening value, she is referred to a health care provider in accordance with the national clinical care guidelines. Abnormal values include:

- Blood pressure: systolic ≥140 mm Hg or diastolic ≥90 mm Hg.
- Nonfasting cholesterol: total cholesterol ≥200 mg/dL or HDL is <40 mg/dL. However, if the woman has normal total cholesterol and HDL, yet has multiple (≥2) risk factors, lipoprotein measurement is recommended as a guide to clinical management.
- Fasting cholesterol: depends on LDL measurement and number of risk factors. For example, both an LDL ≥130 mg/dL with <2 risk factors and an LDL ≥100 mg/dL with ≥2 risk factors are considered abnormal.
- Nonfasting blood glucose (casual): ≥160 mg/dL.
- Fasting blood glucose ≥126 mg/dL.

Alert Values

Alert screening values are measures that are considered dangerously high by the WISEWOMAN program and indicate that a woman should receive immediate medical attention. Alert values are:

- Blood pressure ≥180/110 mmHg
- Blood cholesterol ≥400 mg/dL
- Fasting blood glucose ≥375 mg/dL

Allowable Screening Tests

Screenings are defined as preliminary tests used to detect signs of a disorder that may require further investigation. Screening services are made available through health care facilities or other community-based organizations that can meet CLIA standards and that agree to adhere to national clinical care guidelines. WISEWOMAN funds are allowed to reimburse for screening tests or procedures that provide the following measures:

- Resting pulse
- Blood pressure
- Serum total cholesterol
- HDL-cholesterol (nonfasting)

- Fasting lipid panel (considered diagnostic only)
- Height and weight
- Automated blood chemistry (to assess fasting blood glucose, potassium, calcium, creatinine, uric acid, triglyceride, or micronutrient levels)
- Urine analysis
- Paper and pencil tests, interviews, or computerized methods that measure level of physical activity, dietary intake, smoking, osteoporosis risk status, immunization status, or other chronic disease risk factors or preventable health problems.

Allowable Diagnostic Tests

Diagnostic tests are defined as tests and procedures used to identify a disease state or to aid in a diagnosis. Diagnostic services are made available by a physician but also may be performed by nurses or other health professionals who agree to adhere to national clinical care guidelines. WISEWOMAN funds may be allowed to pay for these diagnostic tests only:

- Fasting lipoprotein analysis
- Fasting blood glucose
- Oral glucose tolerance test (OGTT)

Annual Rescreening

Annual rescreening will occur 12 months (+/- 2 months) after a participant's initial or baseline screening. Each WISEWOMAN participant will have the same screening tests administered and answer the same behavioral or health risk appraisal questions that were asked at her initial screening. These measurements are collected and reported every year that she is enrolled in the program.

Atherogenic Diet

An atherogenic diet is one that is high in saturated fatty acids and dietary cholesterol. ATP III considers an atherogenic diet to be an underlying risk factor for coronary heart disease.

Capacity Building

Before a WISEWOMAN project can influence individuals and organizations to make the changes needed for success, it may require resources, knowledge, and skills above and beyond those it already has. Building capacity for the WISEWOMAN projects includes hiring appropriate staff and developing staff and

providers through training efforts that increase adherence to national clinical care guidelines and intervention protocols. Further, an increase in knowledge and skills regarding the impact of CVD risk factors such as poor diet, inactivity, and tobacco are also needed to build capacity for the WISEWOMAN project.

Cardiovascular Disease
Cardiovascular disease (CVD) is a term used to include high blood pressure, coronary heart disease, and stroke. Some organizations use this term to include diseases of the heart and/or the circulatory system.

Case Management
Case management is a program component that involves establishing, brokering, and sustaining a system of available clinical (screening, diagnostic, and treatment) and support services for all enrolled women who would ultimately be assessed to need case management services. Case management is considered the most intensive intervention in the continuum of care, and it is one of many strategies to improve adherence to national clinical guideline recommendations.

Clinical Follow-up
Clinical follow-up is defined as all medical services (including medical care and support services aimed at improving adherence to medical care and treatment for the identified risk factors) provided to address the results of baseline screening. These services are delivered to the woman before her annual rescreen. Examples include simplifying medication regimens, reminding patients of upcoming medical appointments, and arranging for transportation to medical appointments.

Clinical Tracking
Clinical tracking is the recording and analysis of client data to ensure that a woman enrolled in the program receives timely and appropriate rescreening, diagnosis, and treatment services.

Community Health Worker
A community health worker (CHW) is an indigenous member of a specific population who delivers interventions (provides health promotion and health education services, conducts outreach, advocates for patients and clients, provides social support and community advocacy) in a manner consistent with

local cultural beliefs, practices, and social norms. CHWs have been shown to be effective in promoting primary and secondary prevention messages and services and in increasing access to health care. Their work helps to fill in the gaps in the current health care system.

Coronary Heart Disease

Coronary heart disease is caused by atherosclerosis, the narrowing of the coronary arteries due to fatty build-ups of plaque. It is likely to produce angina pectoris (chest pain), heart attack, or both. Risk factors for CHD include high blood pressure, high blood cholesterol, smoking, obesity, and physical inactivity—all of which can be controlled.

Demonstration Projects

Congress has authorized CDC to fund WISEWOMAN projects to demonstrate the feasibility and effectiveness of providing preventive health services (such as CVD screening and behavioral or lifestyle interventions) for women enrolled in NBCCEDP-sponsored programs.

Enhanced WISEWOMAN Project

The enhanced project is charged to conduct intervention research to test the effectiveness and cost-effectiveness of a behavioral or lifestyle intervention that is grounded in the social and cultural context of the target population and aimed at preventing CVD. In addition, the enhanced project is charged to translate and transfer successful intervention and program strategies to other programs that serve financially disadvantaged women. Enhanced projects are strongly encouraged to work closely with a Prevention Research Center or other university partner.

Evidence-based Intervention
An evidence-based intervention is one that has been evaluated and has demonstrated success in reducing cholesterol, blood pressure, and other indicators and has resulted in positive lifestyle outcomes. The Community Guide to Preventive Services, for example, provides evidence-based recommendations for interventions to increase physical activity.

Health Care Advisory Team
Projects are to work with experts selected to form an interdisciplinary team to provide advice on the direction of the project as well as specific project issues. These experts may include physicians, public health practitioners, nutritionists, interventionists, evaluation staff, participants, and others.

Intervention Follow-up
Intervention follow-up encompasses all services provided outside the formal intervention session/program for the purpose of promoting attendance at intervention sessions and adherence to lifestyle interventions. Examples of these services include maintenance sessions, phone calls to offer support and encouragement, and arrangements for transportation to intervention sessions.

Integrated Program
WISEWOMAN is an integrated program in that its services—including screening, counseling, referral, lifestyle modification interventions, and a comprehensive evaluation—are integrated with existing services and evaluation efforts to provide preventive services to the intended population.

Intervention Process Measures
Intervention process measures allow for monitoring the number and types of intervention sessions a woman has received in order that the dosage level or exposure may be determined.

Intervention Research
In enhanced projects, which are research programs, interventions are rigorously tested to determine which are most feasible and effective for changing diet, physical activity, and/or smoking behaviors within the WISEWOMAN target audience.

Lifestyle Intervention Tracking
Lifestyle intervention tracking is the recording and analysis of client data to ensure that a woman enrolled in the program receives the complete intervention.

Lifestyle Intervention Counseling
All eligible WISEWOMAN participants are provided standardized lifestyle intervention counseling (counseling that uses the same methodology and educational materials across all sites). Nutritionists, health educators, or other qualified health care professionals (including trained community health workers) provide nutrition and physical activity counseling that supports national clinical care recommendations. The counseling may occur in an individual and/or group setting for the purpose of helping the participant identify her individual goals and to provide skills and knowledge needed to help her achieve and sustain heart-healthy behaviors. The participant may also receive counseling on smoking cessation, stress management, osteoporosis prevention, or diabetes management.

Lifestyle intervention counseling sessions
Lifestyle intervention counseling sessions are the encounters or appointments held between the interventionist and participant to transfer the knowledge and skill necessary for behavior change. At the state level WISEWOMAN projects determine the number of core or essential standardized lifestyle intervention counseling sessions needed for individual and program success. Success is based on meeting behavioral goals and objectives.

Medical Nutrition Therapy
ATP III defines medical nutrition therapy (MNT) as the nutrition-related intervention and guidance provided by a nutrition professional. Medical nutrition therapy, as recognized by the American Dietetic Association and according to its guidelines, is delivered by a registered dietitian.

Minimum Data Elements
Minimum data elements (MDEs) are a set of standardized data elements developed and collected to ensure that consistent and complete information on screening location, patient demographic characteristics, screening results, diagnostic procedures, intervention tracking and follow-up, and diet, physical activity, and tobacco assessments are collected on women enrolled in the WISEWOMAN project. These are the data items that are minimally necessary for WISEWOMAN-sponsored projects and the CDC to monitor outcomes. The electronic MDE files are submitted semiannually to CDC or a designated contractor. Projects are encouraged to collect additional data for project management and evaluation purposes.

Monitoring
Monitoring is a quality assurance activity to assess the quality and level of adherence to the project's screening and intervention protocols. Strategies include site visits, audits, and other ongoing evaluation activities.

National Breast and Cervical Cancer Early Detection Program
The National Breast and Cervical Cancer Early Detection Program (NBCCEDP) is a program that focuses on service delivery and early detection. In 1995, the US Congress created WISEWOMAN as a supplemental preventive service program for clients enrolled in the NBCCEDP-funded programs. Through the NBCCEDP infrastructure in 12 project locations, WISEWOMAN services are provided.

Outreach
Outreach activities are strategies used to recruit and enroll eligible women previously not known by WISEWOMAN staff. (By contrast, "inreach activities" are strategies used to enroll eligible women who are already known to the health care facility.)

Performance Indicators
WISEWOMAN has identified performance indicators to assist in monitoring and measuring a project's progress toward achieving program goals. Performance indicators help to identify a project's strengths and its opportunities for further improvement.

Project Period
WISEWOMAN projects are funded for a 3- to 5-year period, as noted in the program announcement's request for application.

Protocol
Protocols are written plans specifying the procedures to be followed by project staff or contractors. Protocols are developed to assure that appropriate care is given to all WISEWOMAN participants.

Referral
Referral is a process whereby a participant is introduced to additional health resources in the community, as in helping a woman find an appropriate provider for further diagnosis after receiving notice that her CVD screening values were abnormal. In addition, a referral may be used to provide a WISEWOMAN participant with a link to the intervention counseling she needs to improve her risk factor status.

Risk Reduction Counseling
Risk reduction counseling provides the participant with an interpretation of the results of screening tests and health-risk-assessment questions. WISEWOMAN strongly recommends that the risk reduction counseling be provided both in writing and orally.

Standard WISEWOMAN Project
The standard WISEWOMAN project is charged to evaluate the effectiveness (to include cost effectiveness) of operational approaches used to conduct WISEWOMAN activities such as outreach; screening for blood pressure and cholesterol and to assess behaviors related to smoking, diet, and physical activity; referral; lifestyle intervention; tracking and follow-up; evaluation; professional and public education; and community engagement.

Therapeutic Lifestyle Changes
The National Cholesterol Education Program's ATP III document recommends the use of dietary therapeutic lifestyle changes (TLCs) to reduce cholesterol in the bloodstream through reduced fat and increased fiber intakes. According to the guidelines, a health care provider should initiate TLCs if a woman's LDL is above goal.

- Diet-related recommendations:

  - Saturated fat <7 percent of calories, cholesterol <200 mg/day
  - Consider increased viscous (soluble) fiber (10-25 g/day) and plan stanols/sterols (2g/day) as therapeutic options to enhance LDL lowering
- Weight management
- Increased physical activity

WISEWOMAN Consultant Group

CDC assembled the WISEWOMAN Consultant Group to advise CDC and its partners on issues relevant to the operation, evaluation, and sustainability of WISEWOMAN. The Group is composed of eight nationally known experts who collectively bring extensive knowledge and experience in cardiovascular disease, women's health, public health practice and preventive medicine, access to care, health behavior and lifestyle interventions, and program evaluation.

WISEWOMAN Program

WISEWOMAN is an acronym that stands for **W**ell **I**ntegrated **S**creening and **E**valuation for **Wom**en **A**cross the **N**ation. The program comprises 12 WISEWOMAN demonstration projects, CDC staff, contractors, and other partners.

Appendix C: JNC VI Quick Reference Card, Guide to Prevention and Treatment of Hypertension Recommendations.

National Institute of Health, The sixth report of the national committee on Prevention, detection, evaluation, and treatment of high blood pressure. *Arch Internal Med* 1997; 157:2413-2446. NIH Publication No. 98-4000.

http://www.nhlbi.nih.gov/guidelines/hypertension/jnc6card.pdf

Appendix D: ATP III's Quick Desk Reference

Department of Health and Human Services, *ATP III's Quick Desk Reference.* Washington, DC: National Institute of Health, National Heart, Lung and Blood Institute, 2001, NIH Publication No 01-3305.

http://www.nhlbi.nih.gov/guidelines/cholesterol/atglance.pdf

Appendix E: American Diabetes Association 2002 Clinical Practice Recommendations, Screening for Diabetes

American Diabetes Association, Screening for Diabetes, *Diabetes Care*, 2002;25 (1):S21—24.

http://care.diabetesjournals.org/cgi/reprint/25/suppl_1/s21.pdf

Appendix F: Nutrition and Physical Activity Interventions to Reduce Cardiovascular Disease Risk in Health Care Settings: A Quantitative Review with a Focus on Women

Wilcox S, Parra-Medina D, Thompson-Robinson M, Will J. Nutrition and Physical Activity Interventions to Reduce Cardiovascular Disease Risk in Health Care Settings: A Quantitative Review with a Focus on Women. *Nutrition Review*. 2001; 59(7):197—214.

Appendix G: WISEWOMAN Program Start-up Checklist

√	Responsibilities		WISEWOMAN Program Start-up Checklist
	State	Local	
Project Administration Tasks			
❒			1. Hire/identify staff to plan and administer program
❒			2. Establish and convene an advisory committee to assist with screening and intervention development
❒			3. Establish program guidelines, based on CDC requirements: • target population/eligibility requirements • services to be provided and protocols • use of program funds • reporting requirements
❒			4. Submit program protocols to CDC for approval. Enhanced projects must also receive Institutional Review Board approval.
❒			5. Develop plan to identify/select clinics to implement program at local level (e.g., competitive application process)
❒			6. Establish contracts between state and local clinics for program implementation
❒			7. Establish payment/reimbursement system between state and local clinics
❒			8. Establish contracts between state and collaborative partners
Project Development Tasks			
❒			1. Establish protocols for CVD clinical services (see Chapters 3, 4, and 7 of the WISEWOMAN Guidance Document)
❒			2. Plan CVD intervention strategy and identify/develop intervention materials for participants (see Chapters 5 and 7 of the WISEWOMAN Guidance Document)
❒			3. Develop program evaluation plans (see Chapter 8 of the WISEWOMAN Guidance Document)
❒			4. Develop program forms and letters (see Chapter 2 of the UNC WISEWOMAN Manual) • participant informed consent form • medical release form • physician referral form • clinical follow-up letters to physicians • clinical follow-up letters to participants • participant enrollment, baseline screening, and

√	Responsibilities		WISEWOMAN Program Start-up Checklist
	State	Local	
			follow-up forms
❒			5. Create centralized database to house participant data from local clinics
❒			6. Develop participant tracking system to ensure timely follow-up of clinic visits, medical referrals, and intervention visits
❒			7. Develop program manual of administrative policies, clinical protocols, quality assurance, and educational resources for local clinics
❒			8. Develop training curriculum on program implementation for local clinics
❒			9. Identify clinical laboratory services (e.g., on-site lab, contract with local lab) (see Chapter 2 of the UNC WISEWOMAN Manual)
❒			10. Identify physicians in community to partner with program and accept medical referrals; contract with physicians to provide care
Project Start-up Tasks			
❒			1. Identify clinic space needed for delivery of clinical services and behavioral intervention
❒			2. Train all staff involved with the administration and/or implementation of the program at local clinics
❒			3. Ensure that local clinics have all necessary program materials for program start-up (e.g., intervention materials, consent forms, participant baseline screening and clinical follow-up forms, etc.)
❒			4. Conduct participant recruitment and community outreach activities
❒			5. Enroll participants and begin providing clinical and intervention services

Source: Adapted from the UNC WISEWOMAN Program Start-up Checklist (UNC, 2001, p.18)

Appendix H: Adverse Events Reporting

WISEWOMAN
SERIOUS ADVERSE EVENT REPORT FORM

Please provide the information requested below and send the form to your CDC Project Officer. The CDC Project Officer will in turn forward this report to CDC's IRB as soon as possible, but no later than seven (7) days in the case of death or life-threatening serious adverse events or within fifteen (15) days after the occurrence of all other forms of serious adverse events.

1. Protocol number:
2. Protocol title:
3. Principal investigator:
   Institute:
   Office:
   Phone:
   FAX:
   E-mail:
4. Date of serious adverse event:
5. Location of serious adverse event (e.g., at clinic, at home, or elsewhere):
6. Was this an unexpected adverse event?
7. Brief description of subject(s) Sex: F Age:
(do not include identifiers) Diagnosis:
8. Brief description of the nature of the serious adverse event (attach description separately if more space is needed):
9. Category (outcome) of the serious adverse event:

[ ] death [ ] disability/incapacity

[ ] life-threatening [ ] congenital anomaly/birth defect

[ ] hospitalization—initial or prolonged [ ] required intervention to prevent permanent impairment

[ ] other:

10. Relationship of serious adverse event to research:

[ ] 1 = Unrelated (clearly not related to the research)

[ ] 2 = Unlikely (doubtfully related to the research)

Patient had received only CVD screening tests in this protocol. Patient health summary indicated significant prior cardiac history.

[ ] 3 = Possible (may be related to the research)

[ ] 4 = Probable (likely related to the research)

[ ] 5 = Definite (clearly related to the research)

11. Have similar adverse events occurred on this protocol? Yes [ ] No [ ]

If *Yes*, how many? ____ Please describe.

12. What steps do you plan to take as a result of the adverse event reported above? Provide documentation to the IRB for review and approval of any of the steps checked below.

[ ] no action required [ ] amend protocol

[ ] amend consent document [ ] inform current subjects

[ ] terminate or suspend protocol

[ ] other (describe):

Signature of principal investigator: _____

Date:_____

Appendix I: Minimum Data Elements and Cost Elements

Minimum Data Elements and Cost Elements

Research Triangle Institute (RTI), our evaluation contractor, is developing a Data User's Guide. This guide will include rationale, data definitions, and edit procedures.

The following Excel spreadsheets contain the file format in which data is reported to RTI. RTI staff will work individually with each WISEWOMAN project to minimize burden and maximize quality.

Cost data is to be determined by staff of project and CDC contractor (Research Triangle Institute). A cost primer that includes activities and reporting elements will be made available to funded projects. However, at this time it is not available through the WISEWOMAN Guidance Document.

Appendix J: Suggested WISEWOMAN Quarterly Progress Report Format

The Request for Application is the source document for identifying activities for which projects are to provide periodic updates. Reports are due 30 days after the reporting period, as follows:

October 31	Covering Dates of July 1 – September 30
January 31	Covering Dates of October 1 – December 31
April 30	Covering Dates of January 1 – March 31
July 31	Covering Dates of April 1 – June 30

Suggested Format for WISEWOMAN QUARTERLY PROGRESS REPORT

I. Please report the status of each recipient activity.

- **A.** Develop a screening and evidence-based intervention program with priority on preventing CVD.
- **B.** Collaborate with other WISEWOMAN programs and partners.
- **C.** Develop program and research protocols.
- **D.** Implement screening, referral, and follow-up IAW recommendations from National Cholesterol Education Program and 6th Joint National Report on the Detection, Evaluation and Treatment of High Blood Pressure. Assure that laboratories are accredited and meet QA standards.
- **E.** Establish CVD prevention as the primary focus of interventions.
- **F.** Implement program/research protocols as developed.
- **G.** Develop abstracts and publications.

II. Major accomplishments (if different from above, for example: hiring status, contract development, etc.).

III. Impact of recipient activities in addressing gaps in surveillance and response capacity (need to answer this question only on the annual progress report.)

IV. Progress toward overall objectives.

A. Provide cholesterol and blood pressure screening to ≥2500 women per year.
B. Implement evidence-based behavioral or lifestyle intervention for the target population.
C. Develop and implement collection methods for evaluation.
D. Develop a system to ensure access to medication.
E. Develop community support for WISEWOMAN program.
F. (Enhanced projects) Obtain statistical power to evaluate program effectiveness.

V. Efforts of proposed strategies to resolve problems.

VI. Changes to the approved work plan.

VII. Amount Funded: _____ Amount Spent: _____

Balance: _____

Explain cost overruns or high-cost items.

VIII. Other.

Table 1 Reporting Project Activities to CDC

Report on a Site-by-Site Basis and Program Total						
Dates Covered (this quarter's dates):	Site 1 Location	Site 2	Site 3	Site 4	Site 5	**Qrtrly Total**
a. Cumulative # WISEWOMAN screened						From inception
b. # BCCEDP screened						This quarter
c. # WISEWOMAN screened (1st time)						This quarter

Report on a Site-by-Site Basis and Program Total						
Dates Covered (this quarter's dates):	Site 1 Location	Site 2	Site 3	Site 4	Site 5	**Qrtrly Total**
d. # WISEWOMAN rescreened						This quarter
e. # participated in nutrition interventions						This quarter
f. # participated in physical activity interventions						This quarter
g. # participated in other intervention:						This quarter
h. # of deaths	Provide a brief summary of patient contacts with deceased.					

Instructions for Completing Table 1

Provide dates that reflect the 3-month period for which the information is reported. Site: Document the location of the site.
Report the following information at the site level. Report the totals for the quarter and provide the total since program inception.

a. Report the cumulative (from inception) number of women screened in the WISEWOMAN program.
b. Report the number of BCCEDP women seen at each site who are eligible for WISEWOMAN services (i.e., aged 40–64 years).
c. Report the number of women who received baseline WISEWOMAN screening.
d. Report the number of women who received annual rescreening.
e. Report the total number of women who participated in nutrition interventions.
f. Report the total number of women who participated in physical activity interventions
g. Report the total number of women who participating in tobacco and/or other interventions.
h. Report the number of women participating in WISEWOMAN who have died. CDC requires that all adverse events be reported.

Table 2 Reporting Alert Value Information to CDC

ALERT VALUES						
Column	1	2	3	4	5	6
RISK FACTORS	n	% referred (n)	Mean days from screen to referral (range)	% seen (n)*	Mean days from screen to visit (range)	% treated with pharmaceuticals (n)**
# Glucose ≥375 mg/dL						
Cholesterol ≥400 mg/dL						
BP ≥180/110 mm Hg						
TOTALS						

*Percentage of those referred

**Percentage of those seen

Referral: Women who have alert blood pressure values and/or glucose values should see a health care provider **immediately or within 1 week,** depending on the clinical situation. Women who have an alert cholesterol level should see a provider within 1 week.

Instructions for Completing Table 2

Provide the following summary information on a quarterly basis to CDC regarding women with alert values.

Column 1: Report the total number of women who have alert values for each of the risk factors.

Column 2: Calculate the number of women referred to medical care and divide by total number of women with alert values (column 1) to determine the percentage of women referred. Also provide the total number.

Column 3: Determine the number of days from screen to referral to medical care for each woman and report the mean and the range for the quarter.

Column 4: Determine the number of women who were referred and who kept their medical appointment and divide by the total number of women with alert values (column 1) and report the percentage and total number.

Column 5: Determine the number of days from the screen to the diagnostic or follow-up visit. Report the mean and the range of days.

Column 6: Of those women seen (column 5) determine the percentage of those prescribed medication. Also provide the total number of women prescribed medication.

If interested, ask you project officer for an Excel spread sheet template to use to capture alert value information.

Table 3 Performance Indicators

Indicator	CDC Standard	Project's Comments
Percentage enrolled in BCCEDP who receive WW screening (BP and cholesterol at a minimum)	2500 screened per year	
Percentage of WISEWOMAN (screened) who return for annual rescreens	≥75%	
Percentage screened who receive reliable oral and printed information about screening results and brief counseling (e.g., risk-reduction counseling)	100%	
Percentage lost to clinical follow-up	≤5%	
Percentage of women, who have abnormal values, who receive referral for lifestyle intervention	100%	
Percentage WW (screened) who have at least one lifestyle intervention encounter***	≥75%	
Percentage of WW (screened) who complete all intervention sessions	≥60%	

Indicator	CDC Standard	Project's Comments
session/counseling***		

***Exception: physician does not release patient to attend intervention

Current CDC standards are adapted from the phase one results of the Massachusetts and North Carolina WISEWOMAN projects. Demonstration projects will help determine future performance indicators and standards as program evaluation occurs.